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OFFICE OF ATTORNEY GENERAL
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PIERRE, SOUTH DAKOTA 57501-8505
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20257112NR-001 - Digital Photo - 20257112 advertisment

Printed on June 13, 2026

20257112 advertisment

Comments:
Subjects:

WEATHER ALERT
Air Quality Alert: Dawes County

KELOLAND.COM ORIGINAL

Abortion pill ads hit South Dakota gas stations

by: Gracie Terrall, Eric Mayer
Posted: Dec 8, 2025 / 05:17 PM CST
Updated: Dec 10, 2025 / 03:55 PM CST

SHARE

Updated: Mayday Health updated their list from 30 gas stations to 14.

SIOUX FALLS, S.D. (KELO) – South Dakotans may notice a new abortion campaign at gas stations around the state.

Starting Monday, Dec. 8, 14 gas stations in 11 South Dakota cities will have abortion pill advertisements as a part of Mayday Health's effort to spread information about the pills and abortion options.

Originally, a list of 30 gas stations were given to KELOLAND News on Monday. However, on Wednesday, Mayday Health sent an updated list with only 14 gas stations listed. A representative from Mayday Health told KELOLAND News on Wednesday that the list of 30 stations was "part of the planning phase, albeit not confirmed" and the list was created by a contractor before the campaign went live.

EXHIBIT
tabbies
B

Kristi Noem responds to replacement rumor >

The signs, posted above gas pumps, read "Pregnant? Don't want to be?" with a link to the organization's website.

"We're putting up ads at gas stations because we think that everyone deserves access to accurate medical information, and gas stations are great places to spread information," Executive Director Liv Raisner told KELOLAND News.

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Rhoden declining to debate Doeden

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Next story in 5

Mayday Health is a national organization with resources and information about abortion care, specifically abortion pills. They've run similar campaigns in Texas, West Virginia and Kentucky as well.

"We believe that it's critical to reach people with health information at community hubs. abortion in rural areas is a privacy issue," Raisner said. "If there's one singular health clinic in the area, people talk.. We want to make sure that people can learn their options anonymously and privately."

According to the Guttmacher Institute, medicated abortions accounted for nearly 63% of abortions in the United States in 2023.

SFPD: 900 snowbird tickets issued after first snow alert >

Raisner said the organization chose South Dakota as their next state for the campaign due to the state's strict abortion laws, but they hope to spread the message abortion abortion pills to every state.

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Under South Dakota's 2006 trigger law, abortion is banned and considered a Class 6 felony punishable by up to two years in prison and up to a $4,000 fine. The only exception to the law is if there is "appropriate and reasonable medical judgment" that an abortion would save the mother's life. There is no exception for rape or incest.

Mayday Health does not provide or ship abortion pills, they just provide information about the options available.

"Our website just gives people the facts about abortion pills and connects them to resources without judgment," Raisner said. "We just want people to have the right information so they can make informed decisions about their own bodies."

Mayday Health also publishes digital ads on social media targeted to states with strict abortion laws and run campaigns with airplanes and boats during heavily populated events like football games, the Indy 500 and outside concerts.

"There's really nowhere we won't go to spread information about abortion pills in states where clinics are banned," Raisner added.

The signs at South Dakota gas stations will be up until January 18.

The owner of Luke Repair in Springfield confirmed that he did agree to display the signs due to the ad revenue it provided, however he said Wednesday that the signs were removed by the wind.

Benny Spies, owner of Cowboy Country Store #3 in Watertown, told KELOLAND News the Mayday Health advertisements won't be on display at his gas station.

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Sara Horning, owner of the Watertown Gas N Goodies, told KELOLAND News she did not authorize the advertisements at her business and will not be allowing them to be displayed.

Wayne Krump, owner of Gas Barrel in Sioux Falls, said he never agreed to display the signs. Gas Barrel was on the original list of 30 gas stations given, but were not included in the updated list of 14 provided on Wednesday.

"We are so pro-life. This hit us hard. We patronize God," Krump said in an interview with KELOLAND News on Wednesday.

Raisner told KELOLAND News all of the gas stations agreed to display the campaign signs. A representative from Mayday Health said they are not able to provide clarification on whether the local store owners or corporate gas stations gave the initial OK.

Gas stations with Mayday Health abortion signs:

Brookings

Classic Corner

Schoon's Pump 'n Pak

Sioux Falls

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King's Liquor, Cliff Avenue

Roadway Travel Center

Local on E Marson Dr.

Volga: AG WRK Co-Op

Renner: Renner Corner Locker

Colome: Flying D

Mitchell: KWIK Phil

Rapid City: Rushmore Sinclair

Springfield: Luke Repair

Summerset: The Pit Stop

Vermillion: Pump 'n Pak

Wagner: Gus Stop

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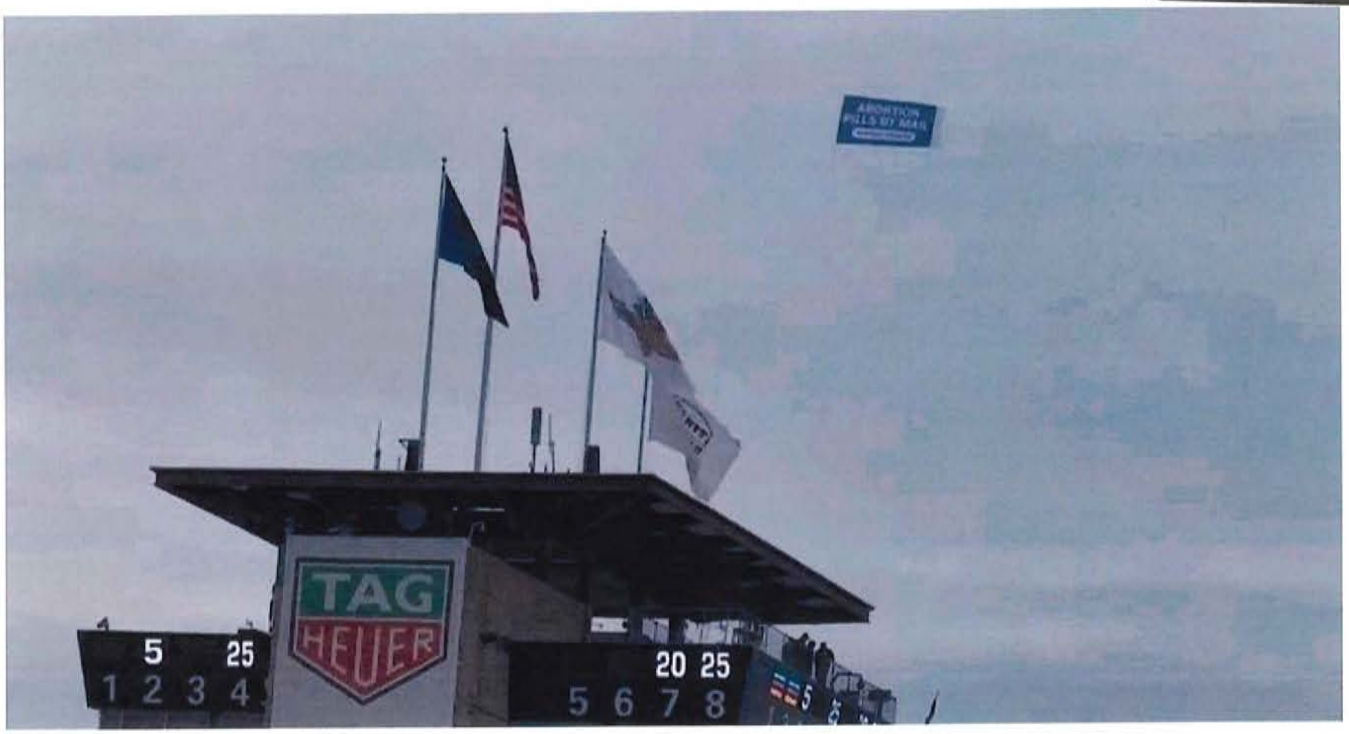
Indiana CAPITAL CHRONICLE

Indy 500 spectators see campaign promoting abortion pill

BY: **MADELYN HANES** - MAY 27, 2025 2:41 PM



A banner adversing abortion pills flew over Indianapolis 500 events over the weekend. (Courtesy Mayday Health)

A plane towing a banner that read 'Abortion pills by mail' flew over the heads of hundreds of thousands of racegoers at the Indianapolis Motor Speedway during Memorial Day weekend.

Mayday Health, an abortion education nonprofit, flew the aerial campaign on Friday's Carb Day, over the Saturday parade and during the race on Sunday. The three-day blitz aimed to inform Hoosiers that despite Indiana's near-total abortion ban, FDA-approved abortion pills remain accessible by mail nationwide.

"Mayday spreads a simple message with many people – abortion pills are available by mail in all 50 states," Mayday Health Founder and Executive Director Liv Raisner said.

Indiana's near-total abortion ban that took effect in August 2023 outlaws abortion except in cases of fatal fetal anomalies and serious health risks to the mother. Victims of rape or incest are also allowed to access abortion care up to 10 weeks post-fertilization. The law mandates that hospitals perform all abortions. While performing an illegal abortion is a felony for doctors in Indiana, women seeking abortions face no criminal penalties.

Raisner said Mayday does not ship the abortion pills but lists providers and connects people with several different resources depending on their needs. From there, individuals who seek

help can consult with a physician who can send the pill through the mail.

The Indianapolis Motor Speedway and Indy 500 had no affiliation with the banner. Under FAA regulations, the agency does not regulate messaging on advertisement banners towed by aircraft. Raisner said the only restriction they had was to stop flying the banner when the cars started their engines shortly after noon.

Reaction

Some posting on social media didn't approve of the message. One poster on X said "Somebody explain to me why there is a plane waving a banner reading "Abortion pills by mail" that is hovering over my head above the infield at the Indy 500 of all places."

Other posters called it "disgusting" and "ridiculous."

But another X post said, "The Indy 500 was surprising pretty progressive. Trump was persona non grata, a non American sang God Bless America and there was an abortion pills by mail banner flying over the track!"

Trump was invited to come to the race but declined with no explanation.

This is not the first abortion campaign to fly over the Indy 500. In 2019, Bloomington-based All-Options Pregnancy Resource Center flew a banner that read "Abortion is OK!" over the Indy 500.

Raisner said the organization takes a "bold-guerilla" approach with their campaigns. Since 2022, Mayday has driven digital billboard trucks to Taylor Swift concerts, sent flyers to rape crisis centers in Tennessee, flown airplanes, driven boats and hosted an abortion pop-up store.

Raisner said Mayday will return to Indy 500 next year and maybe sooner for a future campaign.

"We want to spread the message because there is so much misinformation about abortion pills" they said. "Most people in restricted abortion states don't even know what the laws are for abortion."

Indiana's first full year under the ban shows a total of 146 abortions were performed in Indiana, a 96% decrease from 2022. More than half were performed by using an abortion pill or intracardiac injections.

In June, the U.S. Supreme Court unanimously decided to preserve access to medication, Mifepristone, one of the two drugs used in nearly two-thirds of all abortions in the U.S.

This story was updated to remove an inaccurate reference to Mayday partnering with All Options on the latest campaign.

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MAYDAY.HEALTH

What do you need?

- Abortion
- Morning after pills
- Birth Control
- Gender-Affirming Car

Did you know you can proactively order abortion pills if you're not currently pregnant? Click here for r

Interested in the abortion procedure instead?

Hi, my name's Charley. I can help you get or manage an abortion. / Hola, mi nombre es Charley. Puedo ayudarte a conseguir o manejar un aborto.

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Mayday is a reproductive health education nonprofit

Our Mission >

Additional Resources

Links to trusted organizations.

Before going to any external websites below, you can take these steps for digital privacy.

Abortion decision support >

Abortion pill FAQs ⌄

Plan C

What to expect >

Financial support >

Questions on logistics/delivery times/support while waiting >

Online/phone medical support >

In-person medical support ⌄

Will medical staff know if I've used abortion pills?

Abortion Finder

I Need an A

- Emotional support
- Legal support
- Privacy support
- Reproductive Justice
- State-by-state guide to pills

Donate or Share

Donate Today

Share Us on Social

Mayday Videos

Mayday Featured

The New York Times

TIME

The Atlantic

AP

MPB Mississippi Public Broadcasting

The Guardian

The Washington Post

univision

Bloomberg

teenVOGUE

yahoo!finance

COSMOPOLITAN

NOW THIS

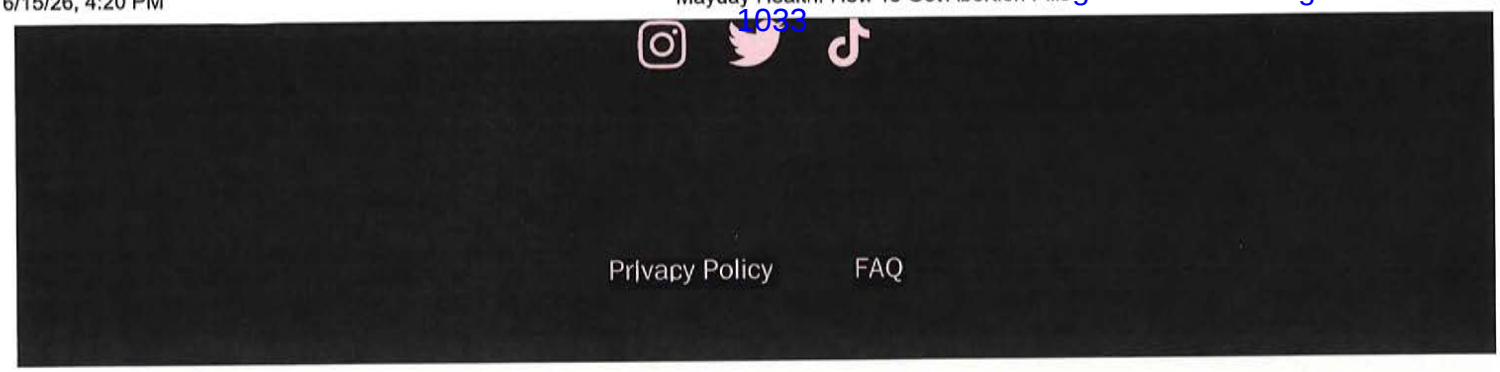
AXIOS

IndyStar.

MAYDAY.HEALTH

Mayday Medicines, Inc. 767 Broadway #1555 New York, New York 10003

For media inquiries only:
media@mayday.health


Privacy Policy
FAQ

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Before going to any external websites below, you can take these steps for digital privacy.

Order from:

Abuzz

SHIPS TO SELECT STATES

COST: SLIDING SCALE

DELIVERY WITHIN 5 DAYS

The MAP

Hi, my name's Charley. I can help you get or manage an abortion. / Hola, mi nombre es Charley. Puedo ayudarte a conseguir o manejar un aborto.

SHIPS TO ALL 50 STATES

COST: SLIDING SCALE

EXHIBIT E

DELIVERY WITHIN 5 DAYS

A Safe Choice

SHIPS TO ALL STATES

COST: $150

DELIVERY WITHIN 4 DAYS

We Take Care of Us

SHIPS TO ALL 50 STATES

COST: SLIDING SCALE

DELIVERY WITHIN 3 BUSINESS DAYS

Aid Access*

Aid Access is experiencing longer delivery times than usual

SHIPS TO ALL 50 STATES

COST: SLIDING SCALE

DELIVERY WITHIN 5 DAYS

FAQs

How are health care providers able to get me pills?

Shield laws offer protection for doctors, nurses and other practitioners in abortion-friendly states who prescribe and send abortion pills to people living in other states that ban or severely restrict abortion. In many states, these laws protect prescribers and patient data, helping patients in other states access abortion pills online from the prescribers. For more information on shield law prescribers, visit the Abortion Coalition for Telemedicine.

Questions about cost, legal risk, and websites we link out to?

Want more information and other ways to get pills?

tor. This site collects **zero data** that could identify a visitor. This site collects **zero data** that could ic

Info on digital privacy, legal concerns, and medical questions

Privacy Guide

Medical Hotline

Legal Helpline

02:53

Mayday Videos

Mayday Featured

The New York Times

TIME

The Atlantic

AP

MPB Mississippi Public Broadcasting

The Guardian

The Washington Post

UNIVISION

Bloomberg

teenVOGUE

yahoo!finance

IndyStar.

AXIOS

COSMOPOLITAN

NOW THIS

MAYDAY.HEALTH

Mayday Medicines, Inc. 767 Broadway #1555 New York, New York 10003

For media inquiries only:
media@mayday.health

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MAYDAY.HEALTH

What do you need?

Al

Mornin

Birt

Gender-A

Did you know you can proa
you're not currently preg

Interested in the abortio

Charley
Online

Charley

Hi, I'm Charley! Please choose a language.

¡Hola, mi nombre es Charley! Por favor elige un idioma.

English Español

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What do you need?

Al

Mornin

Birt

Gender-A

Did you know you can proa
you're not currently preg

Interested in the abortio

Charley
Online

Charley

Thanks!

Anything you tell me here is private, secure, and anonymous. If you close this chat window, the conversation will restart from the beginning.

We can talk as much as you need, but most conversations take 15-20 minutes.

You

Next

Charley

What do you need help with?

Abortion info

Am I pregnant?

EXHIBIT G

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What do you need?

Al

Mornin

Birt

Gender-A

Did you know you can proa
you're not currently preg

Interested in the abortio

Charley
Online

Next

Charley

What do you need help with?

You

Abortion info

Charley

Okay. There are two main types of abortion: abortion pills and abortion procedures.

Both are generally very safe and effective for ending a pregnancy. I can help you choose which type of abortion and how to get care.

Next

This site collects zero data that could identify a visitor.

MAYDAY.HEALTH

What do you need?

Al

Mornin

Birt

Gender-A

Did you know you can proa
you're not currently preg

Interested in the abortio

Charley
Online

Charley

Okay. There are two main types of abortion: abortion pills and abortion procedures.

Both are generally very safe and effective for ending a pregnancy. I can help you choose which type of abortion and how to get care.

You

Next

Charley

Or, if you have already taken abortion pills, I can give you some resources to help. Have you taken abortion pills in the past month (30 days)?

Yes No

EXHIBIT I

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MAYDAY.HEALTH

What do you need?

Al

Mornin

Birt

Gender-A

Did you know you can proa
you're not currently preg

Interested in the abortio

Charley
Online

Next

Charley

Or, if you have already taken abortion pills, I can give you some resources to help. Have you taken abortion pills in the past month (30 days)?

You

No

Charley

Okay. If you already know which type of abortion you're interested in, choose it below.

If you're not sure yet, click "get started".

Get started | Pills | Procedure

EXHIBIT J

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What do you need?

Al

Mornin

Birt

Gender-A

Did you know you can proa
you're not currently preg

Interested in the abortio

Charley
Online

abortion you're interested in, choose it below.

If you're not sure yet, click "get started".

You

Pills

Charley

📌 Do you want a link to a telehealth provider to get pills right now?

🤔 Or would you like more information about how abortion pills work?

⚠️ Which type of abortion is best for you will depend on where you live, how long you have been pregnant, and other things I can explain to help you choose.

Get Pills More Info

EXHIBIT
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What do you need?

Al

Mornin

Birt

Gender-A

Did you know you can proa
you're not currently preg

Interested in the abortio

Charley
Online

📌 Do you want a link to a telehealth provider to get pills right now?

🤔 Or would you like more information about how abortion pills work?

⚠️ Which type of abortion is best for you will depend on where you live, how long you have been pregnant, and other things I can explain to help you choose.

You

Get Pills

Charley

Okay. Abortion pills work best for people less than 13 weeks pregnant. Do you know the date of your last period?

Yes | I'm not sure

EXHIBIT
tabbies
L

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What do you need?

Al

Mornin

Birt

Gender-A

Did you know you can proa
you're not currently preg

Interested in the abortio

Charley
Online

1/1/2026

Charley

Based on your answer, you're likely 23 weeks and 4 days pregnant.

If you are more than 13 weeks pregnant, pills may not be the best option for you. But you may still be able to get an abortion procedure.

Would you like a link to a website where you can find a clinic near you to talk through your options, including abortion procedures?

Or would you like to go back and learn more about the different types of abortion?

Get link Go back

EXHIBIT M

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What do you need?

Al

Mornin

Birt

Gender-A

Did you know you can proa
you're not currently preg

Interested in the abortio

Charley
Online

Would you like a link to a website where you can find a clinic near you to talk through your options, including abortion procedures?

Or would you like to go back and learn more about the different types of abortion?

You

Go back

Charley

Okay. If you already know which type of abortion you're interested in, choose it below.

If you're not sure yet, click "get started".

Get started | Pills | Procedure

EXHIBIT N

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What do you need?

Al

Mornin

Birt

Gender-A

Did you know you can proa
you're not currently preg

Interested in the abortio

Charley
Online

You

4/1/2026

Charley

Based on your answer, you're likely 10 weeks and 5 days pregnant.

This result is less accurate if you have irregular periods, were recently pregnant or are breastfeeding, or have been taking birth control in the last few months.

Here's a website you can use to get abortion pills. AidAccess ships pills to people in all 50 states for $150 or less.

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What do you need?

Al

Mornin

Birt

Gender-A

Did you know you can proa
you're not currently preg

Interested in the abortio

Charley
Online

AidAccess

Get FDA-approved abortion pills from licensed medical providers online now.

Visit website

There are steps you can take to protect your privacy. When using a shared computer or phone, some people who don't want others to know they looked at abortion information, remove the page from their browser history or use "incognito" or private browsing to look at abortion information. Visit reprolegalhelpline.org/internet-safety/ to learn more.

Got it | Learn more

This site collects zero data that could identify a visitor.

MAYDAY.HEALTH

What do you need?

Al

Mornin

Birt

Gender-A

Did you know you can proa
you're not currently preg

Interested in the abortio

Charley
Online

Your abortion options will depend on which location you're searching.

Where would you like to search? Please type in the city and state, or zip code. 🤫 This information is private and secure.

You

Rapid City, SD

Charley

Gotcha, thanks.

Currently, clinics aren't allowed to do abortions in South Dakota. But don't worry! You may still have options, and I can help.

Continue Change location

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What do you need?

Al

Mornin

Birt

Gender-A

Did you know you can proa
you're not currently preg

Interested in the abortio

Charley
Online

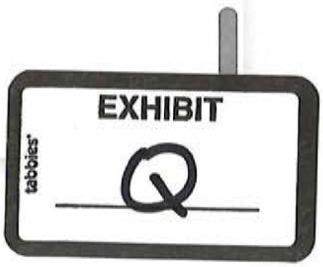
Abortion pills:

Abortion pills can either be two pills (mifepristone and misoprostol) or misoprostol alone. You can take abortion pills on your own time at home or wherever you are comfortable to end a pregnancy. It can take anywhere from a few hours to a few days for the abortion to be complete.

Abortion pills work best in the first 13 weeks of pregnancy. Using pills after 13 weeks can be more painful and less effective. The risk of medical problems also goes up the longer someone is pregnant. Many providers only offer pills up to 10 or 12 weeks.

People can get abortion pills at a clinic, or they can be prescribed online and sent in the mail.

Next



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Mayday is a reproductive health education nonprofit

Our Mission

Our mission is to share information about abortion pills, birth control, and gender-affirming care in any state. We hope to empower people to make their own informed decisions about their own bodies.

Our information comes from top clinicians, lawyers and health experts.

Mayday does not ask for any personal info. We do not track info that could be used to identify a visitor to this website. We do not sell, handle or benefit from abortion pills. We are not affiliated with any telehealth providers. We do not give medical or legal advice.

We just want people to know their options.

MAYDAY.HEALTH

Frequently Asked Questions

What if I'm concerned about the cost? >

What is my legal risk? >

Are abortion pills safe? v

According to the World Health Organization, abortion pills are safe and effective in the first 12 weeks of pregnancy. If you are 12 weeks more pregnant we link to ineedana, a trusted source which has information on abortion procedures and care after 12 weeks.

Why do other buttons send me to other websites? Can I trust them? v

Some of our links go to other websites because they have the best content for a certain aspect of abortion care. We only link to other trusted websites and partners. You can go here to see how to best protect your digital privacy before leaving Mayday.

Mayday Videos

Mayday Featured

The New York Times

TIME

The A . I


The Atlantic


AP


MPB
Mississippi Public Broadcasting


The Guardian


The Washington Post


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Mayday Medicines, Inc. 767 Broadway #1555 New York, New York 10003

For media inquiries only:
media@mayday.health

Privacy Policy FAQ

Legal and safety considerations

Is this legal? Can someone get in trouble for using abortion pills?

- Research shows that hundreds of thousands of people have received and used pills by mail over the past few years with no legal problems.
- But, in rare cases (less than 1%), people have gotten in legal trouble, even though most states don't have laws against doing your own abortion.
- Legal risk can depend on where someone lives, their identity and how far along they are in pregnancy. Also know that even if something isn't a crime, people can still be targeted by law enforcement.

The Repro Legal Helpline provides free, confidential information that can help people better understand legal risk:

Repro Legal Helpline

reprolegalhelpline.org

(844) 868-2812

Ineedana.com also has a state legal directory.

How do people get into trouble?

How do people get in trouble?

Research by the legal organization If/When/How suggests these are the most common ways people have gotten into trouble:

- they told someone about their abortion and that person reported them.
- they got follow-up medical care and the provider reported them (many people say they are having a miscarriage to avoid this risk, which is medically what is happening in the body).
- they were later in pregnancy than they thought and didn't know what to do with the fetal tissue (this calculator can help people understand how pregnant they are).

In the end, it is up to every individual to decide what level of legal risk they are willing to take. Read more about legal risk and find examples here.

What about online activity? Can that get someone in trouble?

People who have been criminalized for accessing or using pills have mostly been reported based on telling someone they know, or via a provider. That said, digital footprints (messages, browser history) also can be used as evidence against someone by authorities. Learn how to protect the privacy of your healthcare information and communications here.

Aid Access

Get abortion and miscarriage care, wherever you are.

An abortion or miscarriage treatment can be done at home with pills or in a clinic with a medical procedure.

Less than 14 weeks pregnant? Get pills shipped to you. The pills are the same ones you get in a clinic. They are medically very safe. The pills are prescribed by a medical professional and packaged in a plain envelope.

Unsure how far along you are? We can help you figure it out.

Get pills

More than 14 weeks pregnant? You will need to have an abortion in a clinic.

Find a clinic

EXHIBIT
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U

← Back to FAQs General Questions

Is it legal?

In the USA

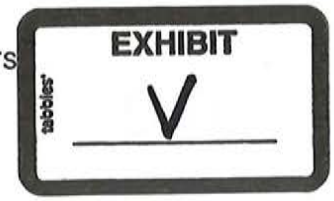
People needing and having abortions in the USA are not breaking the law in any state! We realize there is a lot of confusing information out there. For legal questions or to get legal support call the Repro Legal Helpline at 844-868-2812. Or go to their website reprolegalhelpline.org.

International Situation

The World Health Organization(WHO) listed the abortion medicines mifepristone and misoprostol as essential medicines since 2005.[1]

Access to essential medicines as part of the right to the highest attainable standard of health ("the right to health") is well-founded in numerous international human rights treaties, such as:

1. The Universal Declaration of Human Rights: Article 25.1 in 1948;
2. The International Convention on the Elimination of All Forms of Racial Discrimination; Article 5 (e) (iv) in 1965;
3. The International Covenant on Economic, Social and Cultural Rights: Article 12.1 in 1966;
4. The Convention on the Elimination of All Forms of Discrimination against Women; Articles 11 (1) (f), 12 and 14 (2) (b) in 1979;
5. The 1989 Convention on the Rights of the Child; Article 24;
6. The International Convention on the Protection of the Rights of All Migrant Workers and Members of Their Families; Articles 28, 43 (e) and 45 (c) in 1990;



7. The Convention on the Rights of Persons with Disabilities: Article 25 in 2006.

The authoritative General Comment 14 (2000) further applies the principles of accessibility, availability, appropriateness and assured quality to goods and services, which include essential medicines "as defined by the WHO Action Program on Essential Drugs."[2]

United Nations Report

In October 2011, Anand Grover, the UN Special Rapporteur on the Right to Health, submitted a report to the UN General Assembly which stated, "Criminal laws penalizing and restricting induced abortion are the paradigmatic examples of impermissible barriers to the realization of women's right to health and must be eliminated. These laws infringe women's dignity and autonomy by severely restricting decision-making by women in respect of their sexual and reproductive health."[3]

General comment No. 22 (2016) on the right to sexual and reproductive health (article 12 of the International Covenant on Economic, Social and Cultural Rights) states that, "Essential medicines should also be available, including a wide range of contraceptive methods, such as condoms and emergency contraception, medicines for abortion and for post-abortion care, and medicines, including generic medicines, for the prevention and treatment of sexually transmitted infections and HIV."[4]

World Health Organization

The World Health Organization's definition of health is: "Health is a state of complete physical, mental and social well-being, and not merely the absence of disease or infirmity."[5]

On October 30, 2018, the Human rights committee stated in the General comment No. 36 (2018) on article 6 of the International Covenant on Civil and Political Rights, on the right to life:

"Although States parties may adopt measures designed to regulate voluntary terminations of pregnancy, such measures must not result in violation of the right to life of a pregnant woman or girl, or her other rights under the Covenant. Thus, restrictions on the ability of women or girls to seek abortion must not, inter alia, jeopardize their lives, subject them to physical or mental pain or suffering which violates article 7, discriminate against them or arbitrarily interfere with their privacy. States parties must provide safe, legal and effective

access to abortion where the life and health of the pregnant woman or girl is at risk, and where carrying a pregnancy to term would cause the pregnant woman or girl substantial pain or suffering, most notably where the pregnancy is the result of rape or incest or is not viable. In addition, States parties may not regulate pregnancy or abortion in all other cases in a manner that runs contrary to their duty to ensure that women and girls do not have to undertake unsafe abortions, and they should revise their abortion laws accordingly. For example, they should not take measures such as criminalizing pregnancies by unmarried women or apply criminal sanctions against women and girls undergoing abortion or against medical service providers assisting them in doing so, since taking such measures compel women and girls to resort to unsafe abortion. States parties should not introduce new barriers and should remove existing barriers that deny effective access by women and girls to safe and legal abortion, including barriers caused as a result of the exercise of conscientious objection by individual medical providers. States parties should also effectively protect the lives of women and girls against the mental and physical health risks associated with unsafe abortions. In particular, they should ensure access for women and men, and, especially, girls and boys, to quality and evidence-based information and education about sexual and reproductive health and to a wide range of affordable contraceptive methods, and prevent the stigmatization of women and girls seeking abortion. States parties should ensure the availability of, and effective access to, quality prenatal and post-abortion health care for women and girls, in all circumstances, and on a confidential basis.

Citations

[1] https://apps.who.int/iris/bitstream/handle/10665/325771/WHO-MVP-EMP-IAU-2019.06-eng.pdf?sequence=1&isAllowed=y

[2] https://www.who.int/medicines/areas/human_rights/en/

[3] https://www.un.org/press/en/2011/gashc4018.doc.htm

[4] https://www.ohchr.org/en/press-releases/2009/10/statement-professor-philip-alston-un-special-rapporteur-extrajudicial?LangID=E&NewsID=9219#sthash.MfGe1y5D.XSS87v3P.dpufh

[5] https://apps.who.int/gb/bd/PDF/bd47/EN/constitution-en.pdf?ua=1

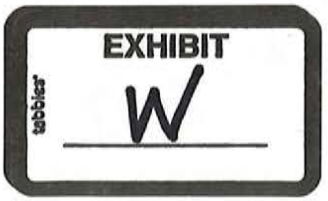
Get Abortion Pills in South Dakota - Order Here

You can buy an abortion pill online and get it by mail in South Dakota. The FDA has approved abortion pills by mail from U.S. based abortion providers for all 50 U.S. states including South Dakota.

Aid Access will help you order abortion pills and get mifepristone and misoprostol tablets delivered to your SD home in Sioux Falls, Rapid City, Aberdeen, Brookings, Watertown, or anywhere else in South Dakota.

South Dakota abortion pill online orders:

- South Dakota abortion pill online orders costs $150 USD
- Reliable abortion pill shipping to South Dakota in 1-5 days
- Tracking numbers provided when the pills are mailed
- Help desk support available in English and Spanish

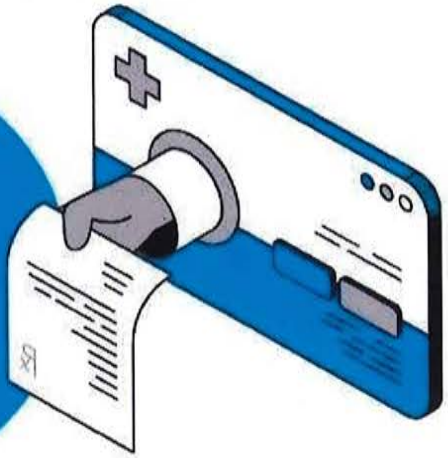


How to get an abortion pill in South Dakota

Submit our online consultation form

1

We need to ask a few questions about your health & pregnancy to ensure you are eligible.



Our doctors will review your order

2

Our medical team will immediately review your consultation and we will email you the next steps.

Receive pills by mail in 1-5 days

3

The abortion pills will be mailed to your address within 24 hours of your order being approved.

AidAccess

How to get abortion pills by mail in South Dakota

You can get a prescription from Aid Access and have abortion pills delivered to your home in South Dakota. **Order abortion pills by mail here.** These are the steps to get abortion pills delivered to your home by mail:

1 Start your online consultation for abortion pills in South Dakota

Once you begin your online consultation for abortion pills in South Dakota, you will be asked some questions about your health and pregnancy to ensure you are eligible. All information you share with us is private and protected.

2 Our U.S. based doctors approve your online abortion pill order

Your consultation will immediately be reviewed by our medical team. Our help desk will email you the next steps, ask you to send a donation of $150 USD, and then approve your online abortion pill order within 24 hours.

3 Receive abortion pills by mail in SD in 1-5 days

The abortion pills will be shipped by mail to your home in SD within 24 hours of your your order being approved. You will receive a tracking number so you can follow your package as it moves through the mail.

Start now: Get the abortion pill online here

How much does the abortion pill cost in South Dakota?

As of 2024, the price of the abortion pill in South Dakota is $150. How much it costs to get abortion pills in South Dakota also changes on a sliding scale so cheaper or free abortion pill kits may be available. Ask our help desk for more info after you submit our free online health screening form.

More ways to get South Dakota abortion pill access

If Aid Access is not able to meet your reproductive health needs, there are multiple ways people get South Dakota abortion pill access. To learn about other online telehealth services that are available to you, visit the Plan C Guide to Abortion Pills: **How to Order an Abortion Pill Online in South Dakota**

South Dakota abortion clinic guides from Plan C Pills

If you determine that abortion pills will not meet your reproductive health needs, you can find information about local abortion support resources near you in the **South Dakota Abortion Clinic Guide** from Plan C Pills.

Additional guides to abortion clinics near South Dakota from Plan C Pills:

Abortion clinics near Sioux Falls, SD

Abortion laws in the State of South Dakota

For the most up to date information about abortion laws in South Dakota, visit **Guttmacher Institute**, **Center for Reproductive Rights**, or **AbortionFinder.org**.

Begin here: Order abortion pills online from Aid Access

Where to buy mifepristone and misoprostol in South Dakota?

Aid access helps people buy mifepristone and misoprostol throughout the state of South Dakota. You can order abortion pills by mail in all of these cities and everywhere in between:

Order the abortion pill in Brookings, South Dakota

If you are in Brookings, you can order the abortion pill here.

Get abortion pills in Aberdeen, South Dakota

If you are in Aberdeen, you can get abortion pills here.

Buy an abortion pill in Rapid City, South Dakota

If you are in Rapid City, you can buy an abortion pill here.

Buy abortion pills in Sioux Falls, South Dakota

If you are in Sioux Falls, you can buy abortion pills here.

Get started: Order an abortion pill online here

WARNING LETTER

Aidaccess.org

MARCS-CMS 575658 — MARCH 08, 2019

More Warning Letters (/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)

Product:

Drugs

Recipient:

Aidaccess.org

United States

Issuing Office:

Center for Drug Evaluation and Research

10903 New Hampshire Ave

Silver Spring, MD 20903

United States

TO: Aidaccess.org

FROM: The United States Food and Drug Administration

RE: Causing the Introduction of a Misbranded and Unapproved New Drug into Interstate Commerce

DATE: March 8, 2019

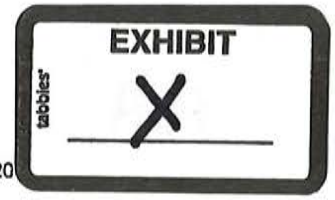
WARNING LETTER

The United States (U.S.) Food and Drug Administration (FDA) recently reviewed your website, http://www.aidaccess.org, and determined that you cause the introduction into interstate commerce of misbranded and unapproved new drugs in violation of sections 301(a), 301(d), and 505(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. §§ 331(a), 331(d), and 355(a)].

The sale of misbranded and unapproved new drugs poses an inherent risk to consumers who purchase those products. Unapproved new drugs do not have the same assurance of safety and effectiveness as those drugs subject to FDA oversight. Drugs that have circumvented regulatory safeguards may be contaminated; counterfeit, contain varying amounts of active ingredients, or contain different ingredients altogether.

FDA requests that you immediately cease causing the introduction of these violative drugs into U.S. commerce.

Unapproved New Drug



Aidaccess.org states on its website, "Aid Access supports women who are not able to access local services. If you are healthy and less than 9 weeks pregnant, you can do the online consultation. The abortion pills mifepristone and misoprostol will be delivered to you by mail." By facilitating the sale of unapproved mifepristone and misoprostol to consumers in the U.S., Aidaccess.org causes the introduction of unapproved new drugs into U.S. commerce in violation of the FD&C Act. These products are drugs within the meaning of section 201(g) of the FD&C Act (21 U.S.C. § 321(g)] because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and/or because they are intended to affect the structure or function of the body. These drugs are also new drugs as defined by section 201(p) of the FD&C Act (21 U.S.C. § 321(p)], because they are not generally recognized as safe and effective for their labeled use. New drugs may not be legally introduced or delivered for introduction into interstate commerce without prior approval from FDA, as described in section 505(a) of the FD&C Act (21 U.S.C. § 355(a)].

Aidaccess.org facilitates the sale to U.S. consumers of unapproved mifepristone in a regimen with unapproved misoprostol labeled for the termination of pregnancy, including "**(b)(4), (b)(6)**," a combination pack that includes both mifepristone and misoprostol tablets. The "**(b)(4), (b)(6)**" product is labeled as a "Combipack of Mifepristone Tablets IP & Misoprostol Tablets IP" and is manufactured by **(b)(4), (b)(6)**. The patient insert accompanying the product states that "**(b)(4), (b)(6)**" is "indicated for early medical abortion for up to 9 weeks." The product labeling states that "**(b)(4), (b)(6)**" is "Marketed by: **(b)(4), (b)(6)**."

No approved applications pursuant to section 505 of the FD&C Act are in effect for this product. Accordingly, its introduction or delivery for introduction into interstate commerce violates sections 301(d) (21 U.S.C. § 331(d)] and 505(a) (21 U.S.C. § 355(a)] of the FD&C Act.

There is an FDA-approved prescription mifepristone drug product that is marketed in the U.S. under the brand name "Mifeprex" and indicated in a regimen with FDA-approved misoprostol, for the termination of early pregnancy (10 weeks or less since last menstrual period began). However, there are no approved drug applications pursuant to section 505 of the FD&C Act in effect for the "**(b)(4), (b)(6)**" product manufactured by **(b)(4), (b)(6)**, caused to be introduced into U.S. commerce via Aidaccess.org.

The substitution of unapproved drugs for FDA-approved prescription drugs poses significant health risks to U.S. consumers. For example, in this case, use of the unapproved drug would not be subject to the same protections as use of the FDA approved product. Mifeprex labeling bears a boxed warning indicating that the drug carries a risk of serious or even life-threatening adverse effects, including serious and sometimes fatal infections and prolonged heavy bleeding, which may be a sign of incomplete abortion or other complications. As further noted in the Mifeprex labeling, Mifeprex is only available in the U.S. through a Risk Evaluation and Mitigation Strategy (REMS) program. The REMS program is intended to mitigate the risk of serious complications associated with Mifeprex by: requiring healthcare providers who prescribe Mifeprex to be certified in the Mifeprex REMS program; ensuring that Mifeprex is only dispensed in certain healthcare settings by or under the supervision of a certified prescriber; and informing patients about the risk of serious complications associated with Mifeprex. Consistent with the REMS, Mifeprex is not sold through retail pharmacies or over the internet. Use of the unapproved "**(b)(4), (b)(6)**" product would not be subject to these FDA-approved REMS provisions.

Misbranded Drug

A drug is misbranded under section 502(f)(l) of the FD&C Act (21 U.S.C. § 352(f)(l)) if it fails to bear adequate directions for its intended use(s). "Adequate directions for use" means directions under which a layperson can use a drug safely and for the purposes for which it is intended (21 CFR 201.5). Prescription drugs, as defined in section 503(b)(l) of the FD&C Act (21 U.S.C. § 353(b)(l)], include those that, because of their toxicity or other potentiality for harmful effect, and/or the method of their use, and/or the collateral measures necessary for their use, are not safe for use except under supervision of a practitioner licensed by law to administer them. Prescription drugs, as defined in section 503(b)(l)(A) of the FD&C Act, can only be used safely at the direction, and under the supervision, of a licensed practitioner.

Because the "**(b)(4), (b)(6)**" product contains prescription drugs intended for a condition that is not amenable to self-diagnosis and treatment by a layperson, adequate directions cannot be written such that a layperson can use the product safely for its intended use. Consequently, the labeling for "**(b)(4), (b)(6)**" fails to bear adequate directions for its intended use, causing it to be misbranded under section 502(f)(l) of the FD&C Act. In addition, because "**(b)(4), (b)(6)**" is not approved in the U.S., it is also not exempt under 21 CFR 201.115(a) from the requirements of section 502(f)(l) of the FD&C Act.

The "**(b)(4), (b)(6)**" product is also misbranded under section 502(f)(2) of the FD&C Act (21 U.S.C. § 352(f)(2)) because it fails to bear "adequate warnings against use ... where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application .... " This is particularly concerning because FDA-approved mifepristone indicated for medical termination of early pregnancy is subject to a REMS program. The REMS program for Mifeprex restricts dispensing to certain healthcare settings, specifically clinics, medical offices, and hospitals, by or under the supervision of a certified prescriber. Healthcare providers who prescribe Mifeprex must be certified in the Mifeprex REMS program. In order to be certified, the prescriber must have the ability to: assess the duration of the pregnancy accurately, diagnose ectopic pregnancies, and provide surgical intervention in cases of incomplete abortion or severe bleeding, or to have made arrangements for others to provide such care. Healthcare providers must be able to ensure that women have access to medical facilities for emergency care, and must agree to other responsibilities, including reviewin& and signing the Patient Agreement Form with the patient and providing each patient with a copy of the signed Patient Agreement Form and the Medication Guide. In addition, the REMS program contains specific requirements for distributors including, but not limited to, following processes and procedures for storage, handling, shipping, tracking package serial numbers, proof of delivery and controlled returns of Mifeprex. By facilitating the sale of the unapproved and misbranded "**(b)(4), (b)(6)**" product, Aldaccess.org is causing important safety measures that are put in place for FDA-approved mifepristone for medical termination of early pregnancy to be bypassed.

By facilitating the sale of "**(b)(4), (b)(6)**" to U.S. consumers, Aldaccess.org is causing the introduction of a misbranded drug into interstate commerce in violation of section 301(a) of the FD&C Act (21 U.S.C. § 331(a)].

***

FDA is taking this action against Aldaccess.org because of the risks posed by its conduct in causing the introduction of a misbranded and unapproved new drug into U.S. commerce. FDA's regulation and oversight of the drug approval process protects consumers by requiring rigorous scientific standards for new drug approval, labeling review for accuracy and completeness, and manufacturing procedures and testing performed under closely controlled conditions at FDA-registered and inspected facilities. Sourcing drugs from outside of the legitimate U.S. drug supply chain can pose serious risks to patients who may receive medications that are adulterated and are not shipped and/or stored properly.

This letter is not intended to identify all the ways in which your activities might be in violation of U.S. law. You should promptly cease causing the sale of unapproved new drugs and misbranded drugs to U.S. consumers and correct all other violations of the FD&C Act. Failure to correct these violations may result in FDA regulatory action, including seizure or injunction, without further notice.

Please notify this office in writing within 15 working days of receipt of this letter of any steps you have taken or will take to correct the violations set forth above and to prevent their recurrence. If the corrective action(s) cannot be completed within 15 working days, state the reason for the delay and the time within which the correction(s) will be completed. If you believe that this product is not in violation of the FD&C Act, include your reasoning and any supporting information for our consideration.

Your response and any other inquiries concerning this letter should be sent to FDA's Internet Pharmacy Task Force at FDAInternetPharmacyTaskForce-CDER@fda.hhs.gov (mailto:FDAInternetPharmacyTaskForce-CDER@fda.hhs.gov).

Sincerely,

/S/

Thomas Christi
Director
Office of Drug Security, Integrity, and Response
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

Cc:
Dr. Rebecca Gomperts
(b)(4), (b)(6)

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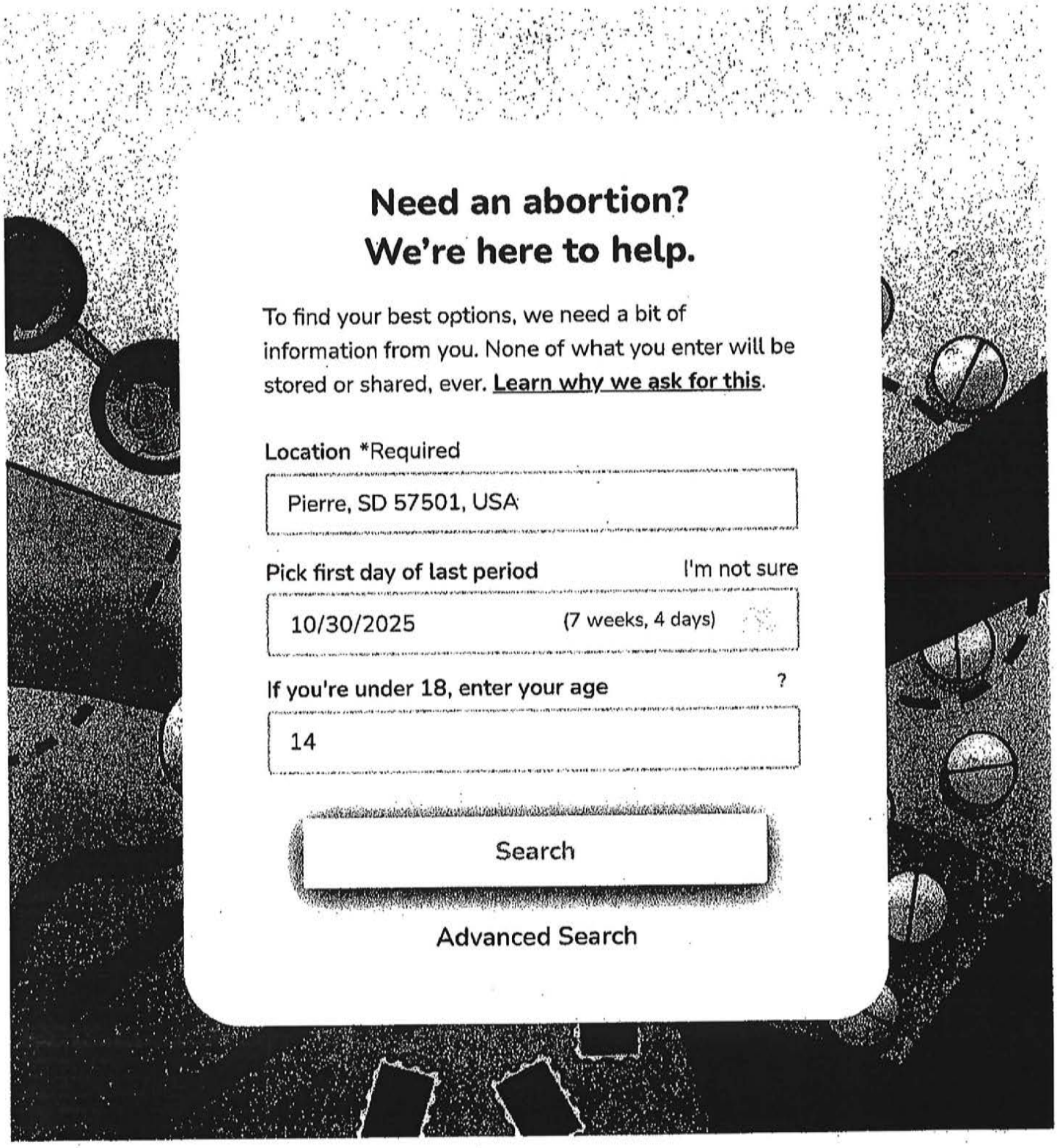

!

EXHIBIT
tabbies
Y

Abortion is banned in South Dakota, but you've still got options.

You are a minor

If you decide to travel for care, you may face additional barriers as a teen.

Learn more in our guide for teens

Open filter menu

Reset filters

Filtered by: 7 weeks or more

6 hrs 6 min drive

Red River Women's Clinic

Moorhead, Minnesota

In-Clinic Procedure Abortion Pills

Go to website (218) 477-3191

More Information

Online

Aid Access via provider in a "shield law" state

This service is verified and medically very safe, but it can come with legal risk in your state.

Pills By Mail

Go to website

~1 hr 40 min direct flight

Fly from Pierre, SD (PIR) to
Denver, Colorado

There are 4 clinics near Denver, Colorado that offer

In-Clinic Procedure Abortion Pills Pills By Mail

up to 33 weeks

More Information

Show more

What are your biggest questions?

How much do abortions cost in South Dakota? ›

What if I need help paying? ›

What's an in-clinic abortion like? >

What happens with abortion pills? >

What are the abortion laws in South Dakota? >

I need help. Who can I talk to? >

The most important thing to know: You're not alone.

People from all walks of life have abortions. These are some of their stories.

video after 15 weeks +9

video written +9

Why was it so complicated for me to get an abortion.. in the...

Video length 50:00

Watch here

video certain +6

Trans people build families and have abortions, too.

Video length 4:40

Watch @ WeTestify

Shout Your Abortion Stories Volume 3

Video length 1:41

Watch @ Shout Your Abortion

See more stories

Your safety and privacy are our top priorities

As such, we'll never ask you for personally identifiable information or store anything you've input.

If you are using a shared device and trying to keep your information private, we recommend you remove this site from your browser history. We can help you learn how to do that and other ways to reduce your digital footprint.

Learn more about privacy

About ineedana.com

Built by people who've had abortions for people who will, ineedana.com launched in 2016 as the first comprehensive and regularly updated resource for abortion seekers in the US. Since then, we've been called the "Quintessential Post-Roe Resource" by The Nation, appeared on John Oliver's Last Week Tonight, and, most importantly to us, have helped more than 1.4 million people learn about their options. As a small and independent non-profit project, we couldn't do it without the support of our volunteers and donors.

Learn more about us | Get involved | Donate

About

Get involved

Blog

Donate

Find all your abortion options

Providers, laws, costs, and support updated daily

Search now

Blog

A Teen's Guide to Accessing Abortion

Posted July 1, 2024

Abortion is safe, normal, and any reason to have one is a good reason. Unfortunately, accessing abortion care can be challenging especially for young people. But you're not alone - we can give you an overview of everything so you can make the best decision for yourself and can connect you with trusted organizations that can help.

Let's start with parental involvement laws, what are they?

There are currently 24 states that require parental notification or consent when a minor is seeking an abortion -- these are called parental involvement laws. In most states, a legal minor is someone who is under 18 years old. **The requirements for parental involvement laws depend on your state and the clinic.** In some states it means the clinic would have to notify your parent or legal guardian. In others, it means your parent or legal guardian must be with you at the clinic to sign consent forms. If you can't find the information at Ineedana.com, calling the local abortion clinic is a great resource or contact the **Repro Legal Helpline** by calling **1-844-868-2812**.

EXHIBIT Z

destination state in the above table, you can call the Repro Legal Helpline at 844-868-2812 for help.

There are also two other options to consider on where to have an abortion:

1. Having medication abortion pills sent to your home (or to a trusted friend/family member) and having an abortion at home.
2. Traveling to a state that does not have parental involvement laws, so you can consent to your own abortion without your parents or a judges' permission.

   Places that don't have parental involvement laws: Alaska, California, Connecticut, Hawaii, Illinois, Maine, Minnesota, Nevada, New Jersey, New Mexico, New York, Oregon, Vermont, Washington, Washington D.C.

   If you are 16 years old or older, you do not need to involve your parents in **Delaware, Massachusetts, and Montana.** If you are 17 years old or older, you do not need parental consent in **South Carolina.**

   Maryland has a parental notification law but can be waived by a doctor. Talk to the clinic for more details.

EXHIBIT Z-0002

MAYDAY IS A 501(C)(3) EDUCATION NONPROFIT.

We are entirely funded by donations and merchandise sales, so your support will help empower people with the education they need to make informed choices about their own bodies and learn how to access abortion pills through the mail in all 50 states.

HOODIES

"All 50 States" Map Cream Hoodie

"All 50 States" Map Black H

"THEY DON'T WANT YOU TO KNOW THIS" HOODIE

$40.00

This high-quality outdoor classic is a steal! It features a double-lined hood and comes in colors for any adventure.

- 50% pre-shrunk cotton, 50% polyester
- Midweight fabric (8.0 oz)
- Regular fit

Select size Size guide

S	M	L	XL
2XL	3XL	4XL	5XL

1

Add to Cart

This site collects zero data that could identify a visitor.

MAYDAY.HEALTH

Donate to Mayday's healthcare education campaign today!

Choose an Amount

Your contribution will benefit Mayday Health.

One-Time Donation

Monthly Donation

$1,000

$500

$250

$100

$50

$25

$10

Choose your own amount

Hi, my name's Charley. I can help you get or manage an abortion. / Hola, mi nombre es Charley. Puedo ayudarte a conseguir o manejar un aborto.

Donate Today!

MAYDAY.HEALTH

Donate to Mayday's healthcare education campaign today!

Choose an Amount

Your contribution will benefit Mayday Health.

One-Time Donation

Monthly Donation

$1,000 $500

$250 $100

$50 $25

Hi, my name's Charley. I can help you get or manage an abortion. / Hola, mi nombre es Charley. Puedo ayudarte a conseguir o manejar un aborto.

$10

Choose your own amount

Donate Today!

Does your employer use Benevity for corporate matching? If so, search for us there to ensure that your emplyer is supporting our work as well!

Mayday Health is a nonprofit that exists to provide information about how people can get mail-order abortion pills, birth control, emergency contraception, and gender affirming care in all 50 states, regardless of harmful state restrictions.

An investment in Mayday is an investment in those who are most harmed by abortion bans.

Your gift helps us do this crucial work. Because of you, we will now be able to reach more people with the life-saving information they need to understand every reproductive health care option available to them – regardless of where they live.

Thank you so much for your tax deductible gift to Mayday Medicines, Inc. (DBA Mayday Health).

Mayday Medicines, Inc. 767 Broadway #1555 New York, New York 10003

Mayday Featured

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TIME

The Atlantic

AP

MPB
Mississippi Public Broadcasting

The Guardian

The Washington Post

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COSMOPOLITAN

NOW THIS

AXIOS

IndyStar.

MAYDAY.HEALTH

Mayday Medicines, Inc. 767 Broadway #1555 New York, New York 10003

For media inquiries only:
media@mayday.health

CURRICULUM VITAE
FOR LEGAL TESTIMONY

Patricia K. Giebink, M.D.

IDENTIFICATION

Name: Patricia K. Giebink, M.D.
Profession: Physician (Obstetrics and Gynecology – Retired)
State of Licensure: South Dakota (1991–2024)
Primary Residence: Chamberlain, South Dakota

PROFESSIONAL SUMMARY

Dr. Patricia K. Giebink is a retired, board-certified obstetrician-gynecologist with over 30 years of clinical experience in women's healthcare. Her professional background includes private practice, hospital-based obstetrics, academic medicine, and service in both domestic and international medical settings. She held admitting privileges in nearly a dozen hospitals across South Dakota and served as an attending physician for the University of South Dakota School of Medicine.

Dr. Giebink also previously worked at Planned Parenthood, the only abortion clinic in South Dakota at the time, giving her direct professional experience relevant to matters involving abortion practice, standards of care, and medical ethics. She is the author of *Unexpected Choice* and frequently provides expert education on women's health and obstetrical care.

EDUCATION AND TRAINING

Internship and Residency, Obstetrics and Gynecology
Indiana University Medical Center, Indianapolis, Indiana (1987–1991)

Doctor of Medicine (M.D.)
University of South Dakota School of Medicine, Vermillion and Sioux Falls, South Dakota (1982–1987)

Master of Science, Physical Education and Exercise Physiology
Montana State University, Bozeman, Montana (1975–1976)

Bachelor of Arts, cum laude, Physical Education and Health
Augustana College, Sioux Falls, South Dakota (1968–1972)

LICENSURE AND CERTIFICATION

Life Fellow, American College of Obstetricians and Gynecologists (2020–Present)
Board Certified, American Board of Obstetrics and Gynecology (1994–2020)

Medical License, State of South Dakota (1991–2024)
Medical License, State of Missouri (2011–2014)
National Board of Medical Examiners – Parts I, II, III, IV (1985–1990)

ACADEMIC APPOINTMENTS

Attending Physician, University of South Dakota School of Medicine
Sioux Falls, South Dakota (1992–1998)

CLINICAL EXPERIENCE

Private Practice, Obstetrics and Gynecology – Sioux Falls, South Dakota
Hospital-Based Obstetrics and Gynecology – Multiple South Dakota hospitals
Locum Tenens Obstetrics – Statewide South Dakota
International Medical Practice – Oasis Hospital, United Arab Emirates
Gynecology Practice – Planned Parenthood Clinic, Sioux Falls, South Dakota

HOSPITAL PRIVILEGES (HISTORICAL)

Sanford Chamberlain Medical Center; Madison Community Hospital; Brookings Health System; Prairie Lakes Hospital; Mid Dakota Hospital; Sioux Valley Hospital; McKennan Hospital; Oasis Hospital (UAE)

PROFESSIONAL SOCIETIES

American College of Obstetricians and Gynecologists (Fellow)
South Dakota State Medical Association
American Association of Prolife Obstetricians and Gynecologists
Sixth District Medical Society
Former Member: Seventh District Medical Society; American Medical Women's Association

HONORS, LEADERSHIP, AND APPOINTMENTS

Executive Board Member, Alpha Center, Sioux Falls, South Dakota
District Six Director and Executive Board Member, AAPLOG
South Dakota Section Chair and Vice-Chair, ACOG
Appointed Member, ACOG Committee on American Indian and Alaskan Native Affairs
South Dakota Representative to ACOG Legislative Workshops
Leadership in Women's Health Policy Conference, UNC–Chapel Hill

PUBLICATIONS

Giebink, P.K. *Unexpected Choice: An Abortion Doctor's Journey to Pro-Life.* Focus on the Family / Tyndale House Publishers.
Author of peer-reviewed medical journal articles.

Information about Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation

Mifeprex (mifepristone) and its generic, Mifepristone Tablets, 200 mg (collectively mifepristone) are approved, in a regimen with misoprostol, to end an intrauterine pregnancy through ten weeks gestation (70 days or less since the first day of a patient's last menstrual period). The FDA first approved Mifeprex in 2000 and approved a generic version of Mifeprex, Mifepristone Tablets, 200 mg, in 2019.

Risk Evaluation and Mitigation Strategy (REMS) Information

Mifeprex and its generic, Mifepristone Tablets, 200 mg, are available under a single, shared system risk evaluation and mitigation strategy (REMS), known as the Mifepristone REMS Program, which sets forth the requirements that must be followed for prescribing and dispensing mifepristone for medical termination of pregnancy through ten weeks gestation.

Under the Mifepristone REMS Program, mifepristone must be prescribed by certified prescribers and must be dispensed by or under the supervision of a certified prescriber or by a certified pharmacy on a prescription issued by a certified prescriber. Under the Mifepristone REMS Program, mifepristone may be dispensed in person or by mail.

Mifeprex was first approved in 2000 with restrictions to assure its safe use. Mifeprex was deemed to have in effect an approved REMS under the Food and Drug Administration Amendments Act of 2007. In 2019, at the same time the FDA approved the generic version of Mifeprex, the agency approved the Mifepristone REMS Program, a single, shared system REMS for mifepristone products for the medical termination of intrauterine pregnancy through 70 days gestation.

In 2021, after conducting a review of the Mifepristone REMS Program, the FDA determined that the available data and information support modification of the REMS to reduce burden on the health care delivery system and to ensure the benefits of the product outweigh the risks. After reviewing supplemental applications from the applicants for Mifeprex and the approved generic, the FDA approved a modification to the Mifepristone REMS Program on January 3, 2023. As modified, the Mifepristone REMS Program includes the following requirements, among others:

- Mifepristone must be prescribed by a health care provider that meets certain qualifications and is certified under the Mifepristone REMS Program.
- In order to become certified to prescribe mifepristone, health care providers must complete a Prescriber Agreement Form.
- The Patient Agreement Form must be reviewed with and signed by the patient and the health care provider, and the risks of the mifepristone treatment regimen must be fully explained to the patient before mifepristone is prescribed.
- The patient must be provided with a copy of the Patient Agreement Form and mifepristone Medication Guide (FDA-approved information for patients).
- Mifepristone may only be dispensed by or under the supervision of a certified prescriber, or by a certified pharmacy on a prescription issued by a certified prescriber.
- To become certified to dispense mifepristone, pharmacies must complete a Pharmacy Agreement Form.
- Certified pharmacies must be able to ship mifepristone using a shipping service that provides tracking information.
- Certified pharmacies must ensure mifepristone is dispensed to the patient in a timely manner.

To learn more, please see Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation (/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation).

FDA Does Not Recommend Buying Mifepristone Online

Mifepristone prescribed under the Mifepristone REMS Program will be dispensed to you by your health care provider (or someone under the supervision of your health care provider), or by a pharmacy to which your health care provider has submitted your prescription. You can ask your health care provider whether they are certified in the Mifepristone REMS Program (or working under the supervision of someone who is). The FDA does not recommend purchasing mifepristone outside of the Mifepristone REMS Program – e.g. buying it online or personally transporting it from a foreign country. If a person does so, they would be bypassing important safeguards specifically designed to protect their health. Prescription medicines that are approved for use in the United States have been reviewed for safety, effectiveness, and quality by the FDA, and are subject to FDA-regulated manufacturing controls, including inspection of manufacturing facilities. Generally, prescription medicines purchased from foreign sources are not the FDA-approved versions. The FDA does not have regulatory oversight of prescription medicines from outside the legitimate U.S. drug supply chain; therefore, the FDA cannot ensure the safety, effectiveness, or quality of those medications.

To learn more about buying drugs safely, please see BeSafeRx: Your Source for Online Pharmacy Information (/drugs/buying-using-medicine-safely/besaferx-your-source-online-pharmacy-information)

Related Information

- Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation (/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifeprex)
- Previous REMS
  - REMS Approved in 2011 (/media/164648/download?attachment)
  - REMS Approved in 2016 (/media/164649/download?attachment)
  - REMS Approved in 2019 (/media/164650/download?attachment)
  - REMS Approved in 2021 (/media/164651/download?attachment)
- Historical Information on Mifepristone (marketed as Mifeprex) (http://wayback.archive-it.org/7993/20161022205309/http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111334.htm) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

Labeling and Other Important Information

Mifeprex (mifepristone)

- Mifeprex Prescribing Information (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/020687Orig1s025Lbl.pdf)
- Mifeprex Medication Guide (https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/020687Orig1s025Lbl.pdf#page=16)
- Mifeprex Patient Agreement Form (https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_01_03_Patient_Agreement_Form.pdf)
- Mifeprex Prescriber Agreement Form (https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_03_23_Prescriber_Agreement_Form_for_Danco_Laboratories_LLC.pdf
- Mifeprex Pharmacy Agreement Form (https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_01_03_Pharmacy_Agreement_Form_Danco_Laboratories.pdf)

Mifepristone Tablets, 200 mg

- Mifepristone Tablets, 200 mg Prescribing Information (/media/164653/download?attachment)
- Mifepristone Tablets, 200 mg Medication Guide (/media/164654/download?attachment)
- Mifepristone Tablets, 200 mg Patient Agreement Form (https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_01_03_Patient_Agreement_Form.pdf)
- Mifepristone Tablets, 200 mg Prescriber Agreement Form (https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_03_23_Prescriber_Agreement_Form_for_GenBioPro_Inc..pdf)
- Mifepristone Tablets, 200 mg Pharmacy Agreement Form (https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_01_03_Pharmacy_Agreement_Form_GenBioPro_Inc.pdf)

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use MIFEPREX safely and effectively. See full prescribing information for MIFEPREX.

MIFEPREX® (mifepristone) tablets, for oral use
Initial U.S. Approval: 2000

WARNING: SERIOUS AND SOMETIMES FATAL INFECTIONS OR BLEEDING

See full prescribing information for complete boxed warning.

Serious and sometimes fatal infections and bleeding occur very rarely following spontaneous, surgical, and medical abortions, including following MIFEPREX use.

- **Atypical Presentation of Infection. Patients with serious bacterial infections and sepsis can present without fever, bacteremia or significant findings on pelvic examination. A high index of suspicion is needed to rule out serious infection and sepsis. (5.1)**
- **Bleeding. Prolonged heavy bleeding may be a sign of incomplete abortion or other complications and prompt medical or surgical intervention may be needed. (5.2)**

MIFEPREX is only available through a restricted program called the MIFEPREX REMS Program (5.3).
Before prescribing MIFEPREX, inform the patient about these risks. Ensure the patient knows whom to call and what to do if she experiences sustained fever, severe abdominal pain, prolonged heavy bleeding, or syncope, or if she experiences abdominal pain or discomfort or general malaise for more than 24 hours after taking misoprostol.
Advise the patient to take the MEDICATION GUIDE with her if she visits an emergency room or another healthcare provider who did not prescribe MIFEPREX, so that provider knows that she is undergoing a medical abortion. (5.1, 5.2)

----------RECENT MAJOR CHANGES----------

Boxed Warning	3/2016
Indications and Usage (1)	3/2016
Dosage and Administration, Dosing Regimen (2.1)	3/2016
Dosage and Administration, Post-treatment Assessment: Day 7 to 14 (2.3)	3/2016
Warnings and Precautions, MIFEPREX REMS Program (5.3)	3/2016
Warnings and Precautions, Ectopic Pregnancy (5.4)	3/2016

----------INDICATIONS AND USAGE----------

MIFEPREX is a progestin antagonist indicated, in a regimen with misoprostol, for the medical termination of intrauterine pregnancy through 70 days gestation. (1)

----------DOSAGE AND ADMINISTRATION----------

- 200 mg MIFEPREX on Day 1, followed 24-48 hours after MIFEPREX dosing by 800 mcg buccal misoprostol. (2.1)
- Instruct the patient what to do if significant adverse reactions occur. (2.2)
- Follow-up is needed to confirm complete termination of pregnancy. (2.3)

----------DOSAGE FORMS AND STRENGTHS----------

Tablets containing 200 mg of mifepristone each, supplied as 1 tablet on one blister card (3)

----------CONTRAINDICATIONS----------

- Confirmed/suspected ectopic pregnancy or undiagnosed adnexal mass (4)
- Chronic adrenal failure (4)
- Concurrent long-term corticosteroid therapy (4)
- History of allergy to mifepristone, misoprostol, or other prostaglandins (4)
- Hemorrhagic disorders or concurrent anticoagulant therapy (4)
- Inherited porphyria (4)
- Intrauterine device (IUD) in place (4)

----------WARNINGS AND PRECAUTIONS----------

- Ectopic pregnancy: Exclude before treatment. (5.4)
- Rhesus immunization: Prevention needed as for surgical abortion. (5.5)

----------ADVERSE REACTIONS----------

Most common adverse reactions (>15%) are nausea, weakness, fever/chills, vomiting, headache, diarrhea, and dizziness. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Danco Laboratories, LLC at 1-877-432-7596 or medicaldirector@earlyoptionpill.com or www.earlyoptionpill.com or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

----------DRUG INTERACTIONS----------

- CYP3A4 inducers can lower mifepristone concentrations. (7.1)
- CYP3A4 inhibitors can increase mifepristone concentrations. Use with caution. (7.2)
- CYP3A4 substrate concentrations can be increased. Caution with coadministration of substrates with narrow therapeutic margin. (7.3)

----------USE IN SPECIFIC POPULATIONS----------

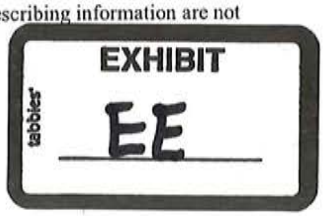
- Pregnancy: Risk of fetal malformations in ongoing pregnancy if not terminated is unknown. (8.1)

See 17 for PATIENT COUNSELING INFORMATION, Medication Guide.

Revised: 3/2016

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.



FULL PRESCRIBING INFORMATION

WARNING: SERIOUS AND SOMETIMES FATAL INFECTIONS OR BLEEDING

Serious and sometimes fatal infections and bleeding occur very rarely following spontaneous, surgical, and medical abortions, including following MIFEPREX use. No causal relationship between the use of MIFEPREX and misoprostol and these events has been established.

- **Atypical Presentation of Infection. Patients with serious bacterial infections (e.g., *Clostridium sordellii*) and sepsis can present without fever, bacteremia, or significant findings on pelvic examination following an abortion. Very rarely, deaths have been reported in patients who presented without fever, with or without abdominal pain, but with leukocytosis with a marked left shift, tachycardia, hemoconcentration, and general malaise. A high index of suspicion is needed to rule out serious infection and sepsis *[see Warnings and Precautions (5.1)]*.**
- **Bleeding. Prolonged heavy bleeding may be a sign of incomplete abortion or other complications and prompt medical or surgical intervention may be needed. Advise patients to seek immediate medical attention if they experience prolonged heavy vaginal bleeding *[see Warnings and Precautions (5.2)]*.**

Because of the risks of serious complications described above, MIFEPREX is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the MIFEPREX REMS Program *[see Warnings and Precautions (5.3)]*.

Before prescribing MIFEPREX, inform the patient about the risk of these serious events. Ensure that the patient knows whom to call and what to do, including going to an Emergency Room if none of the provided contacts are reachable, if she experiences sustained fever, severe abdominal pain, prolonged heavy bleeding, or syncope, or if she experiences abdominal pain or discomfort, or general malaise (including weakness, nausea, vomiting or diarrhea) for more than 24 hours after taking misoprostol.

Advise the patient to take the Medication Guide with her if she visits an emergency room or a healthcare provider who did not prescribe MIFEPREX, so that the provider knows that she is undergoing a medical abortion.

1 INDICATIONS AND USAGE

MIFEPREX is indicated, in a regimen with misoprostol, for the medical termination of intrauterine pregnancy through 70 days gestation.

2 DOSAGE AND ADMINISTRATION

2.1 Dosing Regimen

For purposes of this treatment, pregnancy is dated from the first day of the last menstrual period. The duration of pregnancy may be determined from menstrual history and clinical examination. Assess the pregnancy by ultrasonographic scan if the duration of pregnancy is uncertain or if ectopic pregnancy is suspected.

Remove any intrauterine device ("IUD") before treatment with MIFEPREX begins [*see Contraindications (4)*].

The dosing regimen for MIFEPREX and misoprostol is:

- MIFEPREX 200 mg orally + misoprostol 800 mcg buccally
  - *Day One:* MIFEPREX Administration
    One 200 mg tablet of MIFEPREX is taken in a single oral dose.
  - *Day Two or Three:* Misoprostol Administration (minimum 24-hour interval between MIFEPREX and misoprostol)
    Four 200 mcg tablets (total dose 800 mcg) of misoprostol are taken by the buccal route.

    Tell the patient to place two 200 mcg misoprostol tablets in each cheek pouch (the area between the cheek and gums) for 30 minutes and then swallow any remnants with water or another liquid (see Figure 1).

Figure 1

2 pills between cheek and gum on left side + 2 pills between cheek and gum on right side

Patients taking MIFEPREX must take misoprostol within 24 to 48 hours after taking MIFEPREX. The effectiveness of the regimen may be lower if misoprostol is administered less than 24 hours or more than 48 hours after mifepristone administration.

Because most women will expel the pregnancy within 2 to 24 hours of taking misoprostol *[see Clinical Studies (14)]*, discuss with the patient an appropriate location for her to be when she takes the misoprostol, taking into account that expulsion could begin within 2 hours of administration.

2.2 Patient Management Following Misoprostol Administration

During the period immediately following the administration of misoprostol, the patient may need medication for cramps or gastrointestinal symptoms *[see Adverse Reactions (6)]*.

Give the patient:

- Instructions on what to do if significant discomfort, excessive vaginal bleeding or other adverse reactions occur
- A phone number to call if she has questions following the administration of the misoprostol

- The name and phone number of the healthcare provider who will be handling emergencies.

2.3 Post-treatment Assessment: Day 7 to 14

Patients should follow-up with their healthcare provider approximately 7 to 14 days after the administration of MIFEPREX. This assessment is very important to confirm that complete termination of pregnancy has occurred and to evaluate the degree of bleeding. Termination can be confirmed by medical history, clinical examination, human Chorionic Gonadotropin (hCG) testing, or ultrasonographic scan. Lack of bleeding following treatment usually indicates failure; however, prolonged or heavy bleeding is not proof of a complete abortion.

The existence of debris in the uterus (e.g., if seen on ultrasonography) following the treatment procedure will not necessarily require surgery for its removal.

Women should expect to experience vaginal bleeding or spotting for an average of 9 to 16 days. Women report experiencing heavy bleeding for a median duration of 2 days. Up to 8% of women may experience some type of bleeding for more than 30 days. Persistence of heavy or moderate vaginal bleeding at the time of follow-up, however, could indicate an incomplete abortion.

If complete expulsion has not occurred, but the pregnancy is not ongoing, women may be treated with another dose of misoprostol 800 mcg buccally. There have been rare reports of uterine rupture in women who took Mifeprex and misoprostol, including women with prior uterine rupture or uterine scar and women who received multiple doses of misoprostol within 24 hours. Women who choose to use a repeat dose of misoprostol should have a follow-up visit with their healthcare provider in approximately 7 days to assess for complete termination.

Surgical evacuation is recommended to manage ongoing pregnancies after medical abortion *[see Use in Specific Populations (8.1)]*. Advise the patient whether you will provide such care or will refer her to another provider as part of counseling prior to prescribing MIFEPREX.

2.4 Contact for Consultation

For consultation 24 hours a day, 7 days a week with an expert in mifepristone, call Danco Laboratories at 1-877-4 Early Option (1-877-432-7596).

3 DOSAGE FORMS AND STRENGTHS

Tablets containing 200 mg of mifepristone each, supplied as 1 tablet on one blister card. MIFEPREX tablets are light yellow, cylindrical, and bi-convex tablets, approximately 11 mm in diameter and imprinted on one side with "MF."

4 CONTRAINDICATIONS

- Administration of MIFEPREX and misoprostol for the termination of pregnancy (the "treatment procedure") is contraindicated in patients with any of the following conditions:
  - Confirmed or suspected ectopic pregnancy or undiagnosed adnexal mass (the treatment procedure will not be effective to terminate an ectopic pregnancy) *[see Warnings and Precautions (5.4)]*
  - Chronic adrenal failure (risk of acute renal insufficiency)
  - Concurrent long-term corticosteroid therapy (risk of acute renal insufficiency)

- History of allergy to mifepristone, misoprostol, or other prostaglandins (allergic reactions including anaphylaxis, angioedema, rash, hives, and itching have been reported *[see Adverse Reactions (6.2)]*)
- Hemorrhagic disorders or concurrent anticoagulant therapy (risk of heavy bleeding)
- Inherited porphyrias (risk of worsening or of precipitation of attacks)

- Use of MIFEPREX and misoprostol for termination of intrauterine pregnancy is contraindicated in patients with an intrauterine device ("IUD") in place (the IUD might interfere with pregnancy termination). If the IUD is removed, MIFEPREX may be used.

5 WARNINGS AND PRECAUTIONS

5.1 Infection and Sepsis

As with other types of abortion, cases of serious bacterial infection, including very rare cases of fatal septic shock, have been reported following the use of MIFEPREX *[see Boxed Warning]*. Healthcare providers evaluating a patient who is undergoing a medical abortion should be alert to the possibility of this rare event. A sustained (> 4 hours) fever of 100.4°F or higher, severe abdominal pain, or pelvic tenderness in the days after a medical abortion may be an indication of infection.

A high index of suspicion is needed to rule out sepsis (e.g., from *Clostridium sordellii*) if a patient reports abdominal pain or discomfort or general malaise (including weakness, nausea, vomiting or diarrhea) more than 24 hours after taking misoprostol. Very rarely, deaths have been reported in patients who presented without fever, with or without abdominal pain, but with leukocytosis with a marked left shift, tachycardia, hemoconcentration, and general malaise. No causal relationship between MIFEPREX and misoprostol use and an increased risk of infection or death has been established. *Clostridium sordellii* infections have also been reported very rarely following childbirth (vaginal delivery and caesarian section), and in other gynecologic and non-gynecologic conditions.

5.2 Uterine Bleeding

Uterine bleeding occurs in almost all patients during a medical abortion. Prolonged heavy bleeding (soaking through two thick full-size sanitary pads per hour for two consecutive hours) may be a sign of incomplete abortion or other complications and prompt medical or surgical intervention may be needed to prevent the development of hypovolemic shock. Counsel patients to seek immediate medical attention if they experience prolonged heavy vaginal bleeding following a medical abortion *[see Boxed Warning]*.

Women should expect to experience vaginal bleeding or spotting for an average of 9 to 16 days. Women report experiencing heavy bleeding for a median duration of 2 days. Up to 8% of all subjects may experience some type of bleeding for 30 days or more. In general, the duration of bleeding and spotting increased as the duration of the pregnancy increased.

Decreases in hemoglobin concentration, hematocrit, and red blood cell count may occur in women who bleed heavily.

Excessive uterine bleeding usually requires treatment by uterotonics, vasoconstrictor drugs, surgical uterine evacuation, administration of saline infusions, and/or blood transfusions. Based on data from several large clinical trials, vasoconstrictor drugs were used in 4.3% of all subjects, there was a decrease in hemoglobin of more than 2 g/dL in 5.5% of subjects, and blood transfusions were administered to ≤ 0.1% of subjects. Because heavy bleeding requiring

surgical uterine evacuation occurs in about 1% of patients, special care should be given to patients with hemostatic disorders, hypocoagulability, or severe anemia.

5.3 MIFEPREX REMS Program

MIFEPREX is available only through a restricted program under a REMS called the MIFEPREX REMS Program, because of the risks of serious complications *[see Warnings and Precautions (5.1, 5.2)]*.

Notable requirements of the MIFEPREX REMS Program include the following:

- Prescribers must be certified with the program by completing the Prescriber Agreement Form
- Patients must sign a Patient Agreement Form.
- MIFEPREX must be dispensed to patients only in certain healthcare settings, specifically clinics, medical offices and hospitals by or under the supervision of a certified prescriber

Further information is available at 1-877-4 Early Option (1-877-432-7596).

5.4 Ectopic Pregnancy

MIFEPREX is contraindicated in patients with a confirmed or suspected ectopic pregnancy because MIFEPREX is not effective for terminating ectopic pregnancies *[see Contraindications (4)]*. Healthcare providers should remain alert to the possibility that a patient who is undergoing a medical abortion could have an undiagnosed ectopic pregnancy because some of the expected symptoms experienced with a medical abortion (abdominal pain, uterine bleeding) may be similar to those of a ruptured ectopic pregnancy. The presence of an ectopic pregnancy may have been missed even if the patient underwent ultrasonography prior to being prescribed MIFEPREX.

Women who became pregnant with an IUD in place should be assessed for ectopic pregnancy.

5.5 Rhesus Immunization

The use of MIFEPREX is assumed to require the same preventive measures as those taken prior to and during surgical abortion to prevent rhesus immunization.

6 ADVERSE REACTIONS

The following adverse reactions are described in greater detail in other sections:

- Infection and sepsis *[see Warnings and Precautions (5.1)]*
- Uterine bleeding *[see Warnings and Precautions (5.2)]*

6.1 Clinical Trials Experience

Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in the clinical studies of another drug and may not reflect the rates observed in practice.

Information presented on common adverse reactions relies solely on data from US studies, because rates reported in non-US studies were markedly lower and are not likely generalizable to the US population. In three US clinical studies totaling 1,248 women through 70 days gestation who used mifepristone 200 mg orally followed 24-48 hours later by misoprostol 800 mcg buccally, women reported adverse reactions in diaries and in interviews at the follow-up visit. These studies enrolled generally healthy women of reproductive age without contraindications to mifepristone or misoprostol use according to the MIFEPREX product label.

Gestational age was assessed prior to study enrollment using the date of the woman's last menstrual period, clinical evaluation, and/or ultrasound examination.

About 85% of patients report at least one adverse reaction following administration of MIFEPREX and misoprostol, and many can be expected to report more than one such reaction. The most commonly reported adverse reactions (>15%) were nausea, weakness, fever/chills, vomiting, headache, diarrhea, and dizziness (see Table 1). The frequency of adverse reactions varies between studies and may be dependent on many factors including the patient population and gestational age.

Abdominal pain/cramping is expected in all medical abortion patients and its incidence is not reported in clinical studies. Treatment with MIFEPREX and misoprostol is designed to induce uterine bleeding and cramping to cause termination of an intrauterine pregnancy. Uterine bleeding and cramping are expected consequences of the action of MIFEPREX and misoprostol as used in the treatment procedure. Most women can expect bleeding more heavily than they do during a heavy menstrual period *[see Warnings and Precautions (5.2)]*.

Table 1 lists the adverse reactions reported in U.S. clinical studies with incidence >15% of women.

Table 1
Adverse Reactions Reported in Women Following Administration of Mifepristone (oral) and Misoprostol (buccal) in U.S. Clinical Studies

Adverse Reaction	# US studies	Number of Evaluable Women	Range of frequency (%)	Upper Gestational Age of Studies Reporting Outcome
Nausea	3	1,248	51-75%	70 days
Weakness	2	630	55-58%	63 days
Fever/chills	1	414	48%	63 days
Vomiting	3	1,248	37-48%	70 days
Headache	2	630	41-44%	63 days
Diarrhea	3	1,248	18-43%	70 days
Dizziness	2	630	39-41%	63 days

One study provided gestational-age stratified adverse reaction rates for women who were 57-63 and 64-70 days; there was little difference in frequency of the reported common adverse reactions by gestational age.

Information on serious adverse reactions was reported in six U.S. and four non-U.S. clinical studies, totaling 30,966 women through 70 days gestation who used mifepristone 200 mg orally followed 24-48 hours later by misoprostol 800 mcg buccally. Serious adverse reaction rates were similar between U.S. and non-U.S. studies, so rates from both U.S. and non-U.S. studies are presented. In the U.S. studies, one studied women through 56 days gestation, four through 63 days gestation, and one through 70 days gestation, while in the non-U.S. studies, two studied women through 63 days gestation, and two through 70 days gestation. Serious adverse reactions were reported in <0.5% of women. Information from the U.S. and non-U.S. studies is presented in Table 2.

Table 2
Serious Adverse Reactions Reported in Women Following Administration of Mifepristone (oral) and Misoprostol (buccal) in U.S. and Non-US Clinical Studies

Adverse Reaction	US			Non-US		
	# of studies	Number of Evaluable Women	Range of frequency (%)	# of studies	Number of Evaluable Women	Range of frequency (%)
Transfusion	4	17,774	0.03-0.5%	3	12,134	0-0.1%
Sepsis	1	629	0.2%	1	11,155	<0.01%*
ER visit	2	1,043	2.9-4.6%	1	95	0
Hospitalization Related to Medical Abortion	3	14,339	0.04-0.6%	3	1,286	0-0.7%
Infection without sepsis	1	216	0	1	11,155	0.2%
Hemorrhage	NR	NR	NR	1	11,155	0.1%

NR= Not reported
* This outcome represents a single patient who experienced death related to sepsis.

6.2 Postmarketing Experience

The following adverse reactions have been identified during postapproval use of MIFEPREX and misoprostol. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Infections and infestations: post-abortal infection (including endometritis, endomyometritis, parametritis, pelvic infection, pelvic inflammatory disease, salpingitis)
Blood and the lymphatic system disorders: anemia
Immune system disorders: allergic reaction (including anaphylaxis, angioedema, hives, rash, itching)
Psychiatric disorders: anxiety
Cardiac disorders: tachycardia (including racing pulse, heart palpitations, heart pounding)
Vascular disorders: syncope, fainting, loss of consciousness, hypotension (including orthostatic), light-headedness
Respiratory, thoracic and mediastinal disorders: shortness of breath
Gastrointestinal disorders: dyspepsia
Musculoskeletal, connective tissue and bone disorders: back pain, leg pain
Reproductive system and breast disorders: uterine rupture, ruptured ectopic pregnancy, hematometra, leukorrhea
General disorders and administration site conditions: pain

7 DRUG INTERACTIONS

7.1 Drugs that May Reduce MIFEPREX Exposure (Effect of CYP 3A4 Inducers on MIFEPREX)

CYP450 3A4 is primarily responsible for the metabolism of mifepristone. CYP3A4 inducers such as rifampin, dexamethasone, St. John's Wort, and certain anticonvulsants (such as phenytoin, phenobarbital, carbamazepine) may induce mifepristone metabolism (lowering serum concentrations of mifepristone). Whether this action has an impact on the efficacy of the dose

regimen is unknown. Refer to the follow-up assessment *[see Dosage and Administration (2.3)]* to verify that treatment has been successful.

7.2 Drugs that May Increase MIFEPREX Exposure (Effect of CYP 3A4 Inhibitors on MIFEPREX)

Although specific drug or food interactions with mifepristone have not been studied, on the basis of this drug's metabolism by CYP 3A4, it is possible that ketoconazole, itraconazole, erythromycin, and grapefruit juice may inhibit its metabolism (increasing serum concentrations of mifepristone). MIFEPREX should be used with caution in patients currently or recently treated with CYP 3A4 inhibitors.

7.3 Effects of MIFEPREX on Other Drugs (Effect of MIFEPREX on CYP 3A4 Substrates)

Based on *in vitro* inhibition information, coadministration of mifepristone may lead to an increase in serum concentrations of drugs that are CYP 3A4 substrates. Due to the slow elimination of mifepristone from the body, such interaction may be observed for a prolonged period after its administration. Therefore, caution should be exercised when mifepristone is administered with drugs that are CYP 3A4 substrates and have narrow therapeutic range.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Mifepristone is indicated, in a regimen with misoprostol, for the medical termination of intrauterine pregnancy through 70 days gestation. Risks to pregnant women are discussed throughout the labeling.

Refer to misoprostol labeling for risks to pregnant women with the use of misoprostol.

The risk of adverse developmental outcomes with a continued pregnancy after a failed pregnancy termination with MIFEPREX in a regimen with misoprostol is unknown; however, the process of a failed pregnancy termination could disrupt normal embryo-fetal development and result in adverse developmental effects. Birth defects have been reported with a continued pregnancy after a failed pregnancy termination with MIFEPREX in a regimen with misoprostol. In animal reproduction studies, increased fetal losses were observed in mice, rats, and rabbits and skull deformities were observed in rabbits with administration of mifepristone at doses lower than the human exposure level based on body surface area.

Data

Animal Data

In teratology studies in mice, rats and rabbits at doses of 0.25 to 4.0 mg/kg (less than 1/100 to approximately 1/3 the human exposure based on body surface area), because of the antiprogestational activity of mifepristone,fetal losses were much higher than in control animals. Skull deformaties were detected in rabbit studies at approximately 1/6 the human exposure, although no teratogenic effects of mifepristone have been observed to date in rats or mice. These deformities were most likely due to the mechanical effects of uterine contractions resulting from inhibition of progesterone action.

8.2 Lactation

MIFEPREX is present in human milk. Limited data demonstrate undetectable to low levels of the drug in human milk with the relative (weight-adjusted) infant dose 0.5% or less as compared to maternal dosing. There is no information on the effects of MIFEPREX in a regimen with

misoprostol in a breastfed infant or on milk production. Refer to misoprostol labeling for lactation information with the use of misoprostol. The developmental and health benefits of breast-feeding should be considered along with any potential adverse effects on the breast-fed child from MIFEPREX in a regimen with misoprostol.

8.4 Pediatric Use

Safety and efficacy of MIFEPREX have been established in pregnant females. Data from a clinical study of MIFEPREX that included a subset of 322 females under age 17 demonstrated a safety and efficacy profile similar to that observed in adults.

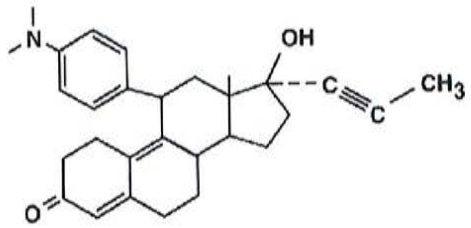
10 OVERDOSAGE

No serious adverse reactions were reported in tolerance studies in healthy non-pregnant female and healthy male subjects where mifepristone was administered in single doses greater than 1800 mg (ninefold the recommended dose for medical abortion). If a patient ingests a massive overdose, she should be observed closely for signs of adrenal failure.

11 DESCRIPTION

MIFEPREX tablets each contain 200 mg of mifepristone, a synthetic steroid with antiprogestational effects. The tablets are light yellow in color, cylindrical, and bi-convex, and are intended for oral administration only. The tablets include the inactive ingredients colloidal silica anhydrous, corn starch, povidone, microcrystalline cellulose, and magnesium stearate.

Mifepristone is a substituted 19-nor steroid compound chemically designated as 11ß-[*p*-(Dimethylamino)phenyl]-17ß-hydroxy-17-(1-propynyl)estra-4,9-dien-3-one. Its empirical formula is $C_{29}H_{35}NO_2$. Its structural formula is:



The compound is a yellow powder with a molecular weight of 429.6 and a melting point of 192-196°C. It is very soluble in methanol, chloroform and acetone and poorly soluble in water, hexane and isopropyl ether.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The anti-progestational activity of mifepristone results from competitive interaction with progesterone at progesterone-receptor sites. Based on studies with various oral doses in several animal species (mouse, rat, rabbit, and monkey), the compound inhibits the activity of endogenous or exogenous progesterone, resulting in effects on the uterus and cervix that, when combined with misoprostol, result in termination of an intrauterine pregnancy.

During pregnancy, the compound sensitizes the myometrium to the contraction-inducing activity of prostaglandins.

12.2 Pharmacodynamics

Use of MIFEPREX in a regimen with misoprostol disrupts pregnancy by causing decidual necrosis, myometrial contractions, and cervical softening, leading to the expulsion of the products of conception.

Doses of 1 mg/kg or greater of mifepristone have been shown to antagonize the endometrial and myometrial effects of progesterone in women.

Antiglucocorticoid and antiandrogenic activity: Mifepristone also exhibits antiglucocorticoid and weak antiandrogenic activity. The activity of the glucocorticoid dexamethasone in rats was inhibited following doses of 10 to 25 mg/kg of mifepristone. Doses of 4.5 mg/kg or greater in human beings resulted in a compensatory elevation of adrenocorticotropic hormone (ACTH) and cortisol. Antiandrogenic activity was observed in rats following repeated administration of doses from 10 to 100 mg/kg.

12.3 Pharmacokinetics

Mifepristone is rapidly absorbed after oral ingestion with non-linear pharmacokinetics for Cmax after single oral doses of 200 mg and 600 mg in healthy subjects.

Absorption

The absolute bioavailability of a 20 mg mifepristone oral dose in women of childbearing age is 69%. Following oral administration of a single dose of 600 mg, mifepristone is rapidly absorbed, with a peak plasma concentration of 1.98 ± 1.0 mg/L occurring approximately 90 minutes after ingestion.

Following oral administration of a single dose of 200 mg in healthy men (n=8), mean Cmax was 1.77 ± 0.7 mg/L occurring approximately 45 minutes after ingestion. Mean $AUC_{0-\infty}$ was 25.8 ± 6.2 mg*hr/L.

Distribution

Mifepristone is 98% bound to plasma proteins, albumin, and α_1-acid glycoprotein. Binding to the latter protein is saturable, and the drug displays nonlinear kinetics with respect to plasma concentration and clearance.

Elimination

Following a distribution phase, elimination of mifepristone is slow at first (50% eliminated between 12 and 72 hours) and then becomes more rapid with a terminal elimination half-life of 18 hours.

Metabolism

Metabolism of mifepristone is primarily via pathways involving N-demethylation and terminal hydroxylation of the 17-propynyl chain. *In vitro* studies have shown that CYP450 3A4 is primarily responsible for the metabolism. The three major metabolites identified in humans are: (1) RU 42 633, the most widely found in plasma, is the N-monodemethylated metabolite; (2) RU 42 848, which results from the loss of two methyl groups from the 4-dimethylaminophenyl in position 11ß; and (3) RU 42 698, which results from terminal hydroxylation of the 17-propynyl chain.

Excretion

By 11 days after a 600 mg dose of tritiated compound, 83% of the drug has been accounted for by the feces and 9% by the urine. Serum concentrations are undetectable by 11 days.

Specific Populations

The effects of age, hepatic disease and renal disease on the safety, efficacy and pharmacokinetics of mifepristone have not been investigated.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis

No long-term studies to evaluate the carcinogenic potential of mifepristone have been performed.

Mutagenesis

Results from studies conducted *in vitro* and in animals have revealed no genotoxic potential for mifepristone. Among the tests carried out were: Ames test with and without metabolic activation; gene conversion test in *Saccharomyces cerevisiae* D4 cells; forward mutation in *Schizosaccharomyces pompe* P1 cells; induction of unscheduled DNA synthesis in cultured HeLa cells; induction of chromosome aberrations in CHO cells; *in vitro* test for gene mutation in V79 Chinese hamster lung cells; and micronucleus test in mice.

Impairment of Fertility

In rats, administration of 0.3 mg/kg mifepristone per day caused severe disruption of the estrus cycles for the three weeks of the treatment period. Following resumption of the estrus cycle, animals were mated and no effects on reproductive performance were observed.

14 CLINICAL STUDIES

Safety and efficacy data from clinical studies of mifepristone 200 mg orally followed 24-48 hours later by misoprostol 800 mcg buccally through 70 days gestation are reported below. Success was defined as the complete expulsion of the products of conception without the need for surgical intervention. The overall rates of success and failure, shown by reason for failure based on 22 worldwide clinical studies (including 7 U.S. studies) appear in Table 3.

The demographics of women who participated in the U.S. clinical studies varied depending on study location and represent the racial and ethnic variety of American females. Females of all reproductive ages were represented, including females less than 18 and more than 40 years of age; most were 27 years or younger.

Table 3
Outcome Following Treatment with Mifepristone (oral) and Misoprostol (buccal) Through 70 Days Gestation

	U.S. Trials	Non-U.S. Trials
N	16,794	18,425
Complete Medical Abortion	97.4%	96.2%
Surgical Intervention*	2.6%	3.8%
Ongoing Pregnancy**	0.7%	0.9%

* Reasons for surgical intervention include ongoing pregnancy, medical necessity, persistent or heavy bleeding after treatment, patient request, or incomplete expulsion.
** Ongoing pregnancy is a subcategory of surgical intervention, indicating the percent of women who have surgical intervention due to an ongoing pregnancy.

The results for clinical studies that reported outcomes, including failure rates for ongoing pregnancy, by gestational age are presented in Table 4.

Table 4
Outcome by Gestational Age Following Treatment with Mifepristone and Misoprostol (buccal) for U.S. and Non-U.S. Clinical Studies

	<49 days			50-56 days			57-63 days			64-70 days		
	N	%	Number of Evaluable Studies	N	%	Number of Evaluable Studies	N	%	Number of Evaluable Studies	N	%	Number of Evaluable Studies
Complete medical abortion	12,046	98.1	10	3,941	96.8	7	2,294	94.7	9	479	92.7	4
Surgical intervention for ongoing pregnancy	10,272	0.3	6	3,788	0.8	6	2,211	2	8	453	3.1	3

One clinical study asked subjects through 70 days gestation to estimate when they expelled the pregnancy, with 70% providing data. Of these, 23-38% reported expulsion within 3 hours and over 90% within 24 hours of using misoprostol.

16 HOW SUPPLIED/STORAGE AND HANDLING

MIFEPREX is only available through a restricted program called the MIFEPREX REMS Program *[see Warnings and Precautions (5.3)]*.

MIFEPREX is supplied as light yellow, cylindrical, and bi-convex tablets imprinted on one side with "MF." Each tablet contains 200 mg of mifepristone. One tablet is individually blistered on one blister card that is packaged in an individual package (National Drug Code 64875-001-01).

Store at 25°C (77°F); excursions permitted to 15 to 30°C (59 to 86°F) [see USP Controlled Room Temperature].

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Medication Guide), included with each package of MIFEPREX. Additional copies of the Medication Guide are available by contacting Danco Laboratories at 1-877-4 Early Option (1-877-432-7596) or from www.earlyoptionpill.com.

Serious Infections and Bleeding

- Inform the patient that uterine bleeding and uterine cramping will occur [see Warnings and Precautions (5.2)].
- Advise the patient that serious and sometimes fatal infections and bleeding can occur very rarely [see Warnings and Precautions (5.1, 5.2)].
- MIFEPREX is only available through a restricted program called the MIFEPREX REMS Program [see Warnings and Precautions (5.3)]. Under the Mifeprex REMS Program:
    - Patients must sign a Patient Agreement Form.
    - MIFEPREX is only available in clinics, medical offices and hospitals and not through retail pharmacies.

Provider Contacts and Actions in Case of Complications

- Ensure that the patient knows whom to call and what to do, including going to an Emergency Room if none of the provided contacts are reachable, or if she experiences complications including prolonged heavy bleeding, severe abdominal pain, or sustained fever *[see Boxed Warning]*.
- Advise the patient to take the Medication Guide with her if she visits an emergency room or another healthcare provider who did not prescribe MIFEPREX, so that provider will be aware that the patient is undergoing a medical abortion with MIFEPREX.

Compliance with Treatment Schedule and Follow-up Assessment

- Advise the patient that it is necessary to complete the treatment schedule, including a follow-up assessment approximately 7 to14 days after taking MIFEPREX *[see Dosage and Administration (2.3)]*.
- Explain that
    - prolonged heavy vaginal bleeding is not proof of a complete abortion,
    - if the treatment fails and the pregnancy continues, the risk of fetal malformation is unknown,
    - it is recommended that ongoing pregnancy be managed by surgical termination *[see Dosage and Administration (2.3)]*. Advise the patient whether you will provide such care or will refer her to another provider.

Subsequent Fertility

- Inform the patient that another pregnancy can occur following medical abortion and before resumption of normal menses.
- Inform the patient that contraception can be initiated as soon as pregnancy expulsion has been confirmed, or before she resumes sexual intercourse.

MIFEPREX is a registered trademark of Danco Laboratories, LLC.

Manufactured for:
Danco Laboratories, LLC
P.O. Box 4816
New York, NY 10185
1-877-4 Early Option (1-877-432-7596)
www.earlyoptionpill.com

3/2016

MEDICATION GUIDE

Mifeprex (MIF-eh-prex) (mifepristone) tablets, for oral use

Read this information carefully before taking Mifeprex and misoprostol. It will help you understand how the treatment works. This Medication Guide does not take the place of talking with your healthcare provider.

What is the most important information I should know about Mifeprex?

What symptoms should I be concerned with? Although cramping and bleeding are an expected part of ending a pregnancy, rarely, serious and potentially life-threatening bleeding, infections, or other problems can occur following a miscarriage, surgical abortion, medical abortion, or childbirth. Seeking medical attention as soon as possible is needed in these circumstances. Serious infection has resulted in death in a very small number of cases. There is no information that use of Mifeprex and misoprostol caused these deaths. If you have any questions, concerns, or problems, or if you are worried about any side effects or symptoms, you should contact your healthcare provider. You can write down your healthcare provider's telephone number here _____.

Be sure to contact your healthcare provider promptly if you have any of the following:

- **Heavy Bleeding.** Contact your healthcare provider right away if you bleed enough to soak through two thick full-size sanitary pads per hour for two consecutive hours or if you are concerned about heavy bleeding. In about 1 out of 100 women, bleeding can be so heavy that it requires a surgical procedure (surgical aspiration or D&C).
- **Abdominal Pain or "Feeling Sick."** If you have abdominal pain or discomfort, or you are "feeling sick," including weakness, nausea, vomiting, or diarrhea, with or without fever, more than 24 hours after taking misoprostol, you should contact your healthcare provider without delay. These symptoms may be a sign of a serious infection or another problem (including an ectopic pregnancy, a pregnancy outside the womb).
- **Fever.** In the days after treatment, if you have a fever of 100.4°F or higher that lasts for more than 4 hours, you should contact your healthcare provider right away. Fever may be a symptom of a serious infection or another problem.

If you cannot reach your healthcare provider, go to the nearest hospital emergency room. Take this Medication Guide with you. When you visit an emergency room or a healthcare provider who did not give you your Mifeprex, you should give them your Medication Guide so that they understand that you are having a medical abortion with Mifeprex.

What to do if you are still pregnant after Mifeprex with misoprostol treatment. If you are still pregnant, your healthcare provider will talk with you about a surgical procedure to end your pregnancy. In many cases, this surgical procedure can be done in the office/clinic. The chance of birth defects if the pregnancy is not ended is unknown.

Talk with your healthcare provider. Before you take Mifeprex, you should read this Medication Guide and you and your healthcare provider should discuss the benefits and risks of your using Mifeprex.

What is Mifeprex?

Mifeprex is used in a regimen with another prescription medicine called misoprostol, to end an early pregnancy. Early pregnancy means it is 70 days (10 weeks) or less since your last menstrual period began. Mifeprex is not approved for ending pregnancies that are further along. Mifeprex blocks a hormone needed for your pregnancy to continue. When you use Mifeprex on Day 1, you also need to take another medicine called misoprostol 24 to 48 hours after you take Mifeprex, to cause the pregnancy to be passed from your uterus.

The pregnancy is likely to be passed from your uterus within 2 to 24 hours after taking Mifeprex and misoprostol. When the pregnancy is passed from the uterus, you will have bleeding and cramping that will likely be heavier than your usual period. About 2 to 7 out of 100 women taking Mifeprex will need a surgical procedure because the pregnancy did not completely pass from the uterus or to stop bleeding.

Who should not take Mifeprex?

Some women should not take Mifeprex. Do not take Mifeprex if you:

- Have a pregnancy that is more than 70 days (10 weeks). Your healthcare provider may do a clinical examination, an ultrasound examination, or other testing to determine how far along you are in pregnancy.
- Are using an IUD (intrauterine device or system). It must be taken out before you take Mifeprex.
- Have been told by your healthcare provider that you have a pregnancy outside the uterus (ectopic pregnancy).
- Have problems with your adrenal glands (chronic adrenal failure).
- Take a medicine to thin your blood.
- Have a bleeding problem.
- Have porphyria.
- Take certain steroid medicines.
- Are allergic to mifepristone, misoprostol, or medicines that contain misoprostol, such as Cytotec or Arthrotec.

Ask your healthcare provider if you are not sure about all your medical conditions before taking this medicine to find out if you can take Mifeprex.

What should I tell my healthcare provider before taking Mifeprex?

Before you take Mifeprex, tell your healthcare provider if you:

- cannot follow-up within approximately 7 to 14 days of your first visit
- are breastfeeding. Mifeprex can pass into your breast milk. The effect of the Mifeprex and misoprostol regimen on the breastfed infant or on milk production is unknown.
- are taking medicines, including prescription and over-the-counter medicines, vitamins, and herbal supplements.
  Mifeprex and certain other medicines may affect each other if they are used together. This can cause side effects.

How should I take Mifeprex?

- Mifeprex will be given to you by a healthcare provider in a clinic, medical office, or hospital.
- You and your healthcare provider will plan the most appropriate location for you to take the misoprostol, because it may cause bleeding, cramps, nausea, diarrhea, and other symptoms that usually begin within 2 to 24 hours after taking it.
- Most women will pass the pregnancy within 2 to 24 hours after taking the misoprostol tablets.

Follow the instruction below on how to take Mifeprex and misoprostol:

Mifeprex (1 tablet) orally + misoprostol (4 tablets) buccally

Day 1:

- Take 1 Mifeprex tablet by mouth.
- Your healthcare provider will either give you or prescribe for you 4 misoprostol tablets to take 24 to 48 hours later.

24 to 48 hours after taking Mifeprex:

- Place 2 misoprostol tablets in each cheek pouch (the area between your teeth and cheek - see Figure A) for 30 minutes and then swallow anything left over with a drink of water or another liquid.
- The medicines may not work as well if you take misoprostol sooner than 24 hours after Mifeprex or later than 48 hours after Mifeprex.
- Misoprostol often causes cramps, nausea, diarrhea, and other symptoms. Your healthcare provider may send you home with medicines for these symptoms.

Figure A (2 tablets between your left cheek and gum and 2 tablets between your right cheek and gum).

Follow-up Assessment at Day 7 to 14:

- This follow-up assessment is very important. You must follow-up with your healthcare provider about 7 to 14 days after you have taken Mifeprex to be sure you are well and that you have had bleeding and the pregnancy has passed from your uterus.
- Your healthcare provider will assess whether your pregnancy has passed from your uterus. If your pregnancy continues, the chance that there may be birth defects is unknown. If you are still pregnant, your healthcare provider will talk with you about a surgical procedure to end your pregnancy.
- If your pregnancy has ended, but has not yet completely passed from your uterus, your provider will talk with you about other choices you have, including waiting, taking another dose of misoprostol, or having a surgical procedure to empty your uterus.

When should I begin birth control?

You can become pregnant again right after your pregnancy ends. If you do not want to become pregnant again, start using birth control as soon as your pregnancy ends or before you start having sexual intercourse again.

What should I avoid while taking Mifeprex and misoprostol?

Do not take any other prescription or over-the-counter medicines (including herbal medicines or supplements) at any time during the treatment period without first asking your healthcare provider about them because they may interfere with the treatment. Ask your healthcare provider about what medicines you can take for pain and other side effects.

What are the possible side effects of Mifeprex and misoprostol?

Mifeprex may cause serious side effects. See "What is the most important information I should know about Mifeprex?"

Cramping and bleeding. Cramping and vaginal bleeding are expected with this treatment. Usually, these symptoms mean that the treatment is working. But sometimes you can get cramping and bleeding and still be pregnant. This is why you must follow-up with your healthcare provider approximately 7 to 14 days after taking Mifeprex. See "How should I take Mifeprex?" for more information on your follow-up assessment. If you are not already bleeding after taking Mifeprex, you probably will begin to bleed once you take misoprostol, the medicine you take 24 to 48 hours after Mifeprex. Bleeding or spotting can be expected for an average of 9 to16 days and may last for up to 30 days. Your bleeding may be similar to, or greater than, a normal heavy period. You may see blood clots and tissue. This is an expected part of passing the pregnancy.

The most common side effects of Mifeprex treatment include: nausea, weakness, fever/chills, vomiting, headache, diarrhea and dizziness. Your provider will tell you how to manage any pain or other side effects.These are not all the possible side effects of Mifeprex.

Call your healthcare provider for medical advice about any side effects that bother you or do not go away. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of Mifeprex.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. This Medication Guide summarizes the most important information about Mifeprex. If you would like more information, talk with your healthcare provider. You may ask your healthcare provider for information about Mifeprex that is written for healthcare professionals.

For more information about Mifeprex, go to www.earlyoptionpill.com or call 1-877-4 Early Option (1-877-432-7596).

Manufactured for: *Danco Laboratories, LLC*
P.O. Box 4816
New York, NY 10185
1-877-4 Early Option (1-877-432-7596) www.earlyoptionpill.com

This Medication Guide has been approved by the U.S. Food and Drug Administration. Approval 3/2016

Cytotec®
misoprostol tablets

WARNINGS

CYTOTEC (MISOPROSTOL) ADMINISTRATION TO WOMEN WHO ARE PREGNANT CAN CAUSE ABORTION, PREMATURE BIRTH, OR BIRTH DEFECTS. UTERINE RUPTURE HAS BEEN REPORTED WHEN CYTOTEC WAS ADMINISTERED IN PREGNANT WOMEN TO INDUCE LABOR OR TO INDUCE ABORTION BEYOND THE EIGHTH WEEK OF PREGNANCY (see also **PRECAUTIONS** and **LABOR AND DELIVERY**). CYTOTEC SHOULD NOT BE TAKEN BY PREGNANT WOMEN TO REDUCE THE RISK OF ULCERS INDUCED BY NONSTEROIDAL ANTI-INFLAMMATORY DRUGS (NSAIDs) (see **CONTRAINDICATIONS**, **WARNINGS**, and **PRECAUTIONS**).

PATIENTS MUST BE ADVISED OF THE ABORTIFACIENT PROPERTY AND WARNED NOT TO GIVE THE DRUG TO OTHERS.

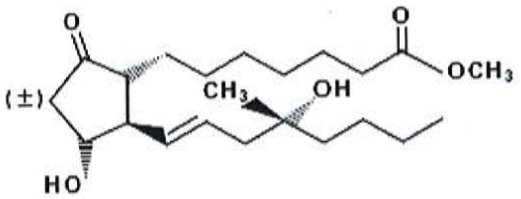
Cytotec should not be used for reducing the risk of NSAID-induced ulcers in women of childbearing potential unless the patient is at high risk of complications from gastric ulcers associated with use of the NSAID, or is at high risk of developing gastric ulceration. In such patients, Cytotec may be prescribed if the patient

- has had a negative serum pregnancy test within 2 weeks prior to beginning therapy.
- is capable of complying with effective contraceptive measures.
- has received both oral and written warnings of the hazards of misoprostol, the risk of possible contraception failure, and the danger to other women of childbearing potential should the drug be taken by mistake.
- will begin Cytotec only on the second or third day of the next normal menstrual period.

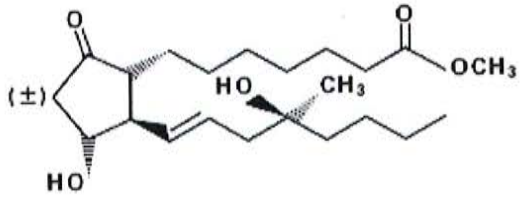
DESCRIPTION

Cytotec oral tablets contain either 100 mcg or 200 mcg of misoprostol, a synthetic prostaglandin E_1 analog.

Misoprostol contains approximately equal amounts of the two diastereomers presented below with their enantiomers indicated by (±):



and



$C_{22}H_{38}O_5$ M.W. = 382.5

(±) methyl 11α,16-dihydroxy-16-methyl-9-oxoprost-13E-en-1-oate

Misoprostol is a water-soluble, viscous liquid.

Inactive ingredients of tablets are hydrogenated castor oil, hypromellose, microcrystalline cellulose, and sodium starch glycolate.

CLINICAL PHARMACOLOGY

Pharmacokinetics: Misoprostol is extensively absorbed, and undergoes rapid de-esterification to its free acid, which is responsible for its clinical activity and, unlike the parent compound, is detectable in plasma. The alpha side chain undergoes beta oxidation and the beta side chain undergoes omega oxidation followed by reduction of the ketone to give prostaglandin F analogs.

In normal volunteers, Cytotec (misoprostol) is rapidly absorbed after oral administration with a T_{max} of misoprostol acid of 12 ± 3 minutes and a terminal half-life of 20–40 minutes.

There is high variability of plasma levels of misoprostol acid between and within studies but mean values after single doses show a linear relationship with dose over the range of 200–400 mcg. No accumulation of misoprostol acid was noted in multiple dose studies; plasma steady state was achieved within two days.

Maximum plasma concentrations of misoprostol acid are diminished when the dose is taken with food and total availability of misoprostol acid is reduced by use of concomitant antacid. Clinical trials were conducted with concomitant antacid, however, so this effect does not appear to be clinically important.

Mean ± SD	C_{max}(pg/ml)	AUC(0–4) (pg·hr/ml)	T_{max}(min)
Fasting	811 ± 317	417 ± 135	14 ± 8
With Antacid	689 ± 315	349 ± 108*	20 ± 14
With High Fat Breakfast	303 ± 176*	373 ± 111	64 ± 79*

* Comparisons with fasting results statistically significant, $p<0.05$.

After oral administration of radiolabeled misoprostol, about 80% of detected radioactivity appears in urine. Pharmacokinetic studies in patients with varying degrees of renal impairment showed an approximate doubling of $T_{1/2}$, C_{max}, and AUC compared to normals, but no clear correlation between the degree of impairment and AUC. In subjects over 64 years of age, the AUC for misoprostol acid is increased. No routine dosage adjustment is recommended in older patients or patients with renal impairment, but dosage may need to be reduced if the usual dose is not tolerated.

Drug interaction studies between misoprostol and several nonsteroidal anti-inflammatory drugs showed no effect on the kinetics of ibuprofen or diclofenac, and a 20% decrease in aspirin AUC, not thought to be clinically significant.

Pharmacokinetic studies also showed a lack of drug interaction with antipyrine and propranolol when these drugs were given with misoprostol. Misoprostol given for 1 week had no effect on the steady state pharmacokinetics of diazepam when the two drugs were administered 2 hours apart.

The serum protein binding of misoprostol acid is less than 90% and is concentration-independent in the therapeutic range.

After a single oral dose of misoprostol to nursing mothers, misoprostol acid was excreted in breast milk. The maximum concentration of misoprostol acid in expressed breast milk was achieved within 1 hour after dosing and was 7.6 pg/ml (CV 37%) and 20.9 pg/ml (CV 62%) after single 200 µg and 600 µg misoprostol administration, respectively. The misoprostol acid concentrations in breast milk declined to < 1 pg/ml at 5 hours post-dose.

Pharmacodynamics: Misoprostol has both antisecretory (inhibiting gastric acid secretion) and (in animals) mucosal protective properties. NSAIDs inhibit prostaglandin synthesis, and a deficiency of prostaglandins within the gastric mucosa may lead to diminishing bicarbonate and mucus secretion and may contribute to the mucosal damage caused by these agents. Misoprostol can increase bicarbonate and mucus production, but in man this has been shown at doses 200 mcg and above that are also antisecretory. It is therefore not possible to tell whether the ability of misoprostol to reduce the risk of gastric ulcer is the result of its antisecretory effect, its mucosal protective effect, or both.

In vitro studies on canine parietal cells using tritiated misoprostol acid as the ligand have led to the identification and characterization of specific prostaglandin receptors. Receptor

binding is saturable, reversible, and stereospecific. The sites have a high affinity for misoprostol, for its acid metabolite, and for other E type prostaglandins, but not for F or I prostaglandins and other unrelated compounds, such as histamine or cimetidine. Receptor-site affinity for misoprostol correlates well with an indirect index of antisecretory activity. It is likely that these specific receptors allow misoprostol taken with food to be effective topically, despite the lower serum concentrations attained.

Misoprostol produces a moderate decrease in pepsin concentration during basal conditions, but not during histamine stimulation. It has no significant effect on fasting or postprandial gastrin nor on intrinsic factor output.

Effects on gastric acid secretion: Misoprostol, over the range of 50–200 mcg, inhibits basal and nocturnal gastric acid secretion, and acid secretion in response to a variety of stimuli, including meals, histamine, pentagastrin, and coffee. Activity is apparent 30 minutes after oral administration and persists for at least 3 hours. In general, the effects of 50 mcg were modest and shorter lived, and only the 200-mcg dose had substantial effects on nocturnal secretion or on histamine and meal-stimulated secretion.

Uterine effects: Cytotec has been shown to produce uterine contractions that may endanger pregnancy. (See boxed **WARNINGS.**)

Other pharmacologic effects: Cytotec does not produce clinically significant effects on serum levels of prolactin, gonadotropins, thyroid-stimulating hormone, growth hormone, thyroxine, cortisol, gastrointestinal hormones (somatostatin, gastrin, vasoactive intestinal polypeptide, and motilin), creatinine, or uric acid. Gastric emptying, immunologic competence, platelet aggregation, pulmonary function, or the cardiovascular system are not modified by recommended doses of Cytotec.

Clinical studies: In a series of small short-term (about 1 week) placebo-controlled studies in healthy human volunteers, doses of misoprostol were evaluated for their ability to reduce the risk of NSAID-induced mucosal injury. Studies of 200 mcg q.i.d. of misoprostol with tolmetin and naproxen, and of 100 and 200 mcg q.i.d. with ibuprofen, all showed reduction of the rate of significant endoscopic injury from about 70–75% on placebo to 10–30% on misoprostol. Doses of 25–200 mcg q.i.d. reduced aspirin-induced mucosal injury and bleeding.

Reducing the risk of gastric ulcers caused by nonsteroidal anti-inflammatory drugs (NSAIDs): Two 12-week, randomized, double-blind trials in osteoarthritic patients who had gastrointestinal symptoms but no ulcer on endoscopy while taking an NSAID compared the ability of 200 mcg of Cytotec, 100 mcg of Cytotec, and placebo to reduce the risk of gastric ulcer (GU) formation. Patients were approximately equally divided between ibuprofen, piroxicam, and naproxen, and continued this treatment throughout the 12 weeks. The 200-mcg dose caused a marked, statistically significant reduction in gastric ulcers in both studies. The lower dose was somewhat less effective, with a significant result in only one of the studies.

Reduction of Risk of Gastric Ulcers Induced by Ibuprofen, Piroxicam, or Naproxen
[No. of patients with ulcer(s) (%)]

Therapy	Therapy Duration			
	4 weeks	8 weeks	12 weeks	
Study No. 1				
Cytotec 200 mcg q.i.d. (n=74)	1 (1.4)	0	0	1 (1.4)*
Cytotec 100 mcg q.i.d. (n=77)	3 (3.9)	1 (1.3)	1 (1.3)	5 (6.5)*
Placebo (n=76)	11 (14.5)	4 (5.3)	4 (5.3)	19 (25.0)
Study No. 2				
Cytotec 200 mcg q.i.d. (n=65)	1 (1.5)	1 (1.5)	0	2 (3.1)*
Cytotec 100 mcg q.i.d. (n=66)	2 (3.0)	2 (3.0)	1 (1.5)	5 (7.6)
Placebo (n=62)	6 (9.7)	2 (3.2)	3 (4.8)	11 (17.7)
*Studies No. 1 & No. 2***				
Cytotec 200 mcg q.i.d. (n=139)	2 (1.4)	1 (0.7)	0	3 (2.2)*
Cytotec 100 mcg q.i.d. (n=143)	5 (3.5)	3 (2.1)	2 (1.4)	10 (7.0)*
Placebo (n=138)	17 (12.3)	6 (4.3)	7 (5.1)	30 (21.7)

* Statistically significantly different from placebo at the 5% level.
** Combined data from Study No. 1 and Study No. 2.

In these trials there were no significant differences between Cytotec and placebo in relief of day or night abdominal pain. No effect of Cytotec in reducing the risk of duodenal ulcers was demonstrated, but relatively few duodenal lesions were seen.

In another clinical trial, 239 patients receiving aspirin 650–1300 mg q.i.d. for rheumatoid arthritis who had endoscopic evidence of duodenal and/or gastric inflammation were randomized to misoprostol 200 mcg q.i.d. or placebo for 8 weeks while continuing to receive aspirin. The study evaluated the possible interference of Cytotec on the efficacy of aspirin in these patients with rheumatoid arthritis by analyzing joint tenderness, joint swelling, physician's clinical assessment, patient's assessment, change in ARA classification, change in handgrip strength, change in duration of morning stiffness, patient's assessment of pain at rest, movement, interference with daily activity, and ESR. Cytotec did not interfere with the efficacy of aspirin in these patients with rheumatoid arthritis.

INDICATIONS AND USAGE

Cytotec (misoprostol) is indicated for reducing the risk of NSAID (nonsteroidal anti-inflammatory drugs, including aspirin)–induced gastric ulcers in patients at high risk of complications from gastric ulcer, e.g., the elderly and patients with concomitant debilitating disease, as well as patients at high risk of developing gastric ulceration, such

as patients with a history of ulcer. Cytotec has not been shown to reduce the risk of duodenal ulcers in patients taking NSAIDs. Cytotec should be taken for the duration of NSAID therapy. Cytotec has been shown to reduce the risk of gastric ulcers in controlled studies of 3 months' duration. It had no effect, compared to placebo, on gastrointestinal pain or discomfort associated with NSAID use.

CONTRAINDICATIONS

See boxed **WARNINGS.**

Cytotec should not be taken by pregnant women to reduce the risk of ulcers induced by nonsteroidal anti-inflammatory drugs (NSAIDs).

Cytotec should not be taken by anyone with a history of allergy to prostaglandins.

WARNINGS

See boxed **WARNINGS.**

PRECAUTIONS

Caution should be employed when administering Cytotec (misoprostol) to patients with pre-existing cardiovascular disease.

Information for patients: Women of childbearing potential using Cytotec to decrease the risk of NSAID-induced ulcers should be told that they must not be pregnant when Cytotec therapy is initiated, and that they must use an effective contraception method while taking Cytotec.

See boxed **WARNINGS.**

Cytotec is intended for administration along with nonsteroidal anti-inflammatory drugs (NSAIDs), including aspirin, to decrease the chance of developing an NSAID-induced gastric ulcer.

Cytotec should be taken only according to the directions given by a physician.

If the patient has questions about or problems with Cytotec, the physician should be contacted promptly.

THE PATIENT SHOULD NOT GIVE CYTOTEC TO ANYONE ELSE. Cytotec has been prescribed for the patient's specific condition, may not be the correct treatment for another person, and may be dangerous to the other person if she were to become pregnant.

The Cytotec package the patient receives from the pharmacist will include a leaflet containing patient information. The patient should read the leaflet before taking Cytotec and each time the prescription is renewed because the leaflet may have been revised.

Keep Cytotec out of the reach of children.

SPECIAL NOTE FOR WOMEN: Cytotec may cause abortion (sometimes incomplete), premature labor, or birth defects if given to pregnant women.

Cytotec is available only as a unit-of-use package that includes a leaflet containing patient information. See *Patient Information* at the end of this labeling.

Drug interactions: See *Clinical Pharmacology.* Cytotec has not been shown to interfere with the beneficial effects of aspirin on signs and symptoms of rheumatoid arthritis. Cytotec does not exert clinically significant effects on the absorption, blood levels, and antiplatelet effects of therapeutic doses of aspirin. Cytotec has no clinically significant effect on the kinetics of diclofenac or ibuprofen.

Animal toxicology: A reversible increase in the number of normal surface gastric epithelial cells occurred in the dog, rat, and mouse. No such increase has been observed in humans administered Cytotec for up to 1 year.

An apparent response of the female mouse to Cytotec in long-term studies at 100 to 1000 times the human dose was hyperostosis, mainly of the medulla of sternebrae. Hyperostosis did not occur in long-term studies in the dog and rat and has not been seen in humans treated with Cytotec.

Carcinogenesis, mutagenesis, impairment of fertility: There was no evidence of an effect of Cytotec on tumor occurrence or incidence in rats receiving daily doses up to 150 times the human dose for 24 months. Similarly, there was no effect of Cytotec on tumor occurrence or incidence in mice receiving daily doses up to 1000 times the human dose for 21 months. The mutagenic potential of Cytotec was tested in several *in vitro* assays, all of which were negative.

Misoprostol, when administered to breeding male and female rats at doses 6.25 times to 625 times the maximum recommended human therapeutic dose, produced dose-related pre- and post-implantation losses and a significant decrease in the number of live pups born at the highest dose. These findings suggest the possibility of a general adverse effect on fertility in males and females.

Pregnancy: Pregnancy Category X.
Teratogenic effects: See boxed **WARNINGS.** Congenital anomalies sometimes associated with fetal death have been reported subsequent to the unsuccessful use of misoprostol as an abortifacient, but the drug's teratogenic mechanism has not been demonstrated. Several reports in the literature associate the use of misoprostol during the first trimester of pregnancy with skull defects, cranial nerve palsies, facial malformations, and limb defects.

Cytotec is not fetotoxic or teratogenic in rats and rabbits at doses 625 and 63 times the human dose, respectively.

Nonteratogenic effects: See boxed **WARNINGS**. Cytotec may endanger pregnancy (may cause abortion) and thereby cause harm to the fetus when administered to a pregnant woman. Cytotec may produce uterine contractions, uterine bleeding, and expulsion of the products of conception. Abortions caused by Cytotec may be incomplete. If a woman is or becomes pregnant while taking this drug to reduce the risk of NSAID-induced ulcers, the drug should be discontinued and the patient apprised of the potential hazard to the fetus.

Labor and delivery: Cytotec can induce or augment uterine contractions. Vaginal administration of Cytotec, outside of its approved indication, has been used as a cervical ripening agent, for the induction of labor and for treatment of serious postpartum hemorrhage in the presence of uterine atony. A major adverse effect of the obstetrical use of Cytotec is the hyperstimulation of the uterus which may progress to uterine tetany with marked impairment of uteroplacental blood flow, uterine rupture (requiring surgical repair, hysterectomy, and/or salpingo-oophorectomy), or amniotic fluid embolism. Pelvic pain, retained placenta, severe genital bleeding, shock, fetal bradycardia, and fetal and maternal death have been reported.

There may be an increased risk of uterine tachysystole, uterine rupture, meconium passage, meconium staining of amniotic fluid, and Cesarean delivery due to uterine hyperstimulation with the use of higher doses of Cytotec, including the manufactured 100 mcg tablet. The risk of uterine rupture increases with advancing gestational ages and with prior uterine surgery, including Cesarean delivery. Grand multiparity also appears to be a risk factor for uterine rupture.

The effect of Cytotec on later growth, development, and functional maturation of the child when Cytotec is used for cervical ripening or induction of labor has not been established. Information on Cytotec's effect on the need for forceps delivery or other intervention is unknown.

Nursing mothers: Misoprostol is rapidly metabolized in the mother to misoprostol acid, which is biologically active and is excreted in breast milk. There are no published reports of adverse effects of misoprostol in breast-feeding infants of mothers taking misoprostol. Caution should be exercised when misoprostol is administered to a nursing woman.

Pediatric use: Safety and effectiveness of Cytotec in pediatric patients have not been established.

ADVERSE REACTIONS

The following have been reported as adverse events in subjects receiving Cytotec:

Gastrointestinal: In subjects receiving Cytotec 400 or 800 mcg daily in clinical trials, the most frequent gastrointestinal adverse events were diarrhea and abdominal pain. The incidence of diarrhea at 800 mcg in controlled trials in patients on NSAIDs ranged from

14–40% and in all studies (over 5,000 patients) averaged 13%. Abdominal pain occurred in 13–20% of patients in NSAID trials and about 7% in all studies, but there was no consistent difference from placebo.

Diarrhea was dose related and usually developed early in the course of therapy (after 13 days), usually was self-limiting (often resolving after 8 days), but sometimes required discontinuation of Cytotec (2% of the patients). Rare instances of profound diarrhea leading to severe dehydration have been reported. Patients with an underlying condition such as inflammatory bowel disease, or those in whom dehydration, were it to occur, would be dangerous, should be monitored carefully if Cytotec is prescribed. The incidence of diarrhea can be minimized by administering after meals and at bedtime, and by avoiding coadministration of Cytotec with magnesium-containing antacids.

Gynecological: Women who received Cytotec during clinical trials reported the following gynecological disorders: spotting (0.7%), cramps (0.6%), hypermenorrhea (0.5%), menstrual disorder (0.3%) and dysmenorrhea (0.1%). Postmenopausal vaginal bleeding may be related to Cytotec administration. If it occurs, diagnostic workup should be undertaken to rule out gynecological pathology. (See boxed **WARNINGS.**)

Elderly: There were no significant differences in the safety profile of Cytotec in approximately 500 ulcer patients who were 65 years of age or older compared with younger patients.

Additional adverse events which were reported are categorized as follows:

Incidence greater than 1%: In clinical trials, the following adverse reactions were reported by more than 1% of the subjects receiving Cytotec and may be causally related to the drug: nausea (3.2%), flatulence (2.9%), headache (2.4%), dyspepsia (2.0%), vomiting (1.3%), and constipation (1.1%). However, there were no significant differences between the incidences of these events for Cytotec and placebo.

Causal relationship unknown: The following adverse events were infrequently reported. Causal relationships between Cytotec and these events have not been established but cannot be excluded:

Body as a whole: aches/pains, asthenia, fatigue, fever, chills, rigors, weight changes.

Skin: rash, dermatitis, alopecia, pallor, breast pain.

Special senses: abnormal taste, abnormal vision, conjunctivitis, deafness, tinnitus, earache.

Respiratory: upper respiratory tract infection, bronchitis, bronchospasm, dyspnea, pneumonia, epistaxis.

Cardiovascular: chest pain, edema, diaphoresis, hypotension, hypertension, arrhythmia, phlebitis, increased cardiac enzymes, syncope, myocardial infarction (some fatal), thromboembolic events (e.g., pulmonary embolism, arterial thrombosis, and CVA).

Gastrointestinal: GI bleeding, GI inflammation/infection, rectal disorder, abnormal hepatobiliary function, gingivitis, reflux, dysphagia, amylase increase.

Hypersensitivity: anaphylactic reaction

Metabolic: glycosuria, gout, increased nitrogen, increased alkaline phosphatase.

Genitourinary: polyuria, dysuria, hematuria, urinary tract infection.

Nervous system/Psychiatric: anxiety, change in appetite, depression, drowsiness, dizziness, thirst, impotence, loss of libido, sweating increase, neuropathy, neurosis, confusion.

Musculoskeletal: arthralgia, myalgia, muscle cramps, stiffness, back pain.

Blood/Coagulation: anemia, abnormal differential, thrombocytopenia, purpura, ESR increased.

OVERDOSAGE

The toxic dose of Cytotec in humans has not been determined. Cumulative total daily doses of 1600 mcg have been tolerated, with only symptoms of gastrointestinal discomfort being reported. In animals, the acute toxic effects are diarrhea, gastrointestinal lesions, focal cardiac necrosis, hepatic necrosis, renal tubular necrosis, testicular atrophy, respiratory difficulties, and depression of the central nervous system. Clinical signs that may indicate an overdose are sedation, tremor, convulsions, dyspnea, abdominal pain, diarrhea, fever, palpitations, hypotension, or bradycardia. Symptoms should be treated with supportive therapy.

It is not known if misoprostol acid is dialyzable. However, because misoprostol is metabolized like a fatty acid, it is unlikely that dialysis would be appropriate treatment for overdosage.

DOSAGE AND ADMINISTRATION

The recommended adult oral dose of Cytotec for reducing the risk of NSAID-induced gastric ulcers is 200 mcg four times daily with food. If this dose cannot be tolerated, a dose of 100 mcg can be used. (See *Clinical Pharmacology: Clinical studies.*) Cytotec should be taken for the duration of NSAID therapy as prescribed by the physician. Cytotec should be taken with a meal, and the last dose of the day should be at bedtime.

Renal impairment: Adjustment of the dosing schedule in renally impaired patients is not routinely needed, but dosage can be reduced if the 200-mcg dose is not tolerated. (See *Clinical Pharmacology.*)

HOW SUPPLIED

Cytotec 100-mcg tablets are white, round, with SEARLE debossed on one side and 1451 on the other side; supplied as:

NDC Number	Size
0025-1451-60	unit-of-use bottle of 60
0025-1451-20	unit-of-use bottle of 120
0025-1451-34	carton of 100 unit dose

Cytotec 200-mcg tablets are white, hexagonal, with SEARLE debossed above and 1461 debossed below the line on one side and a double stomach debossed on the other side; supplied as:

NDC Number	Size
0025-1461-60	unit-of-use bottle of 60
0025-1461-31	unit-of-use bottle of 100
0025-1461-34	carton of 100 unit dose

Store at or below 25°C (77°F), in a dry area.

PATIENT INFORMATION

Read this leaflet before taking Cytotec® (misoprostol) and each time your prescription is renewed, because the leaflet may be changed.

Cytotec (misoprostol) is being prescribed by your doctor to decrease the chance of getting stomach ulcers related to the arthritis/pain medication that you take.

Do not take Cytotec to reduce the risk of NSAID-induced ulcers if you are pregnant. (See boxed **WARNINGS**.) Cytotec can cause abortion (sometimes incomplete which could lead to dangerous bleeding and require hospitalization and surgery), premature birth, or birth defects. It is also important to avoid pregnancy while taking this medication and for at least one month or through one menstrual cycle after you stop taking it. Cytotec has been reported to cause the uterus to rupture (tear) when given after the eighth week of pregnancy. Rupture (tearing) of the uterus can result in severe bleeding, hysterectomy, and/or maternal or fetal death.

If you become pregnant during Cytotec therapy, stop taking Cytotec and contact your physician immediately. Remember that even if you are on a means of birth control it is still possible to become pregnant. Should this occur, stop taking Cytotec and contact your physician immediately.

Cytotec may cause diarrhea, abdominal cramping, and/or nausea in some people. In most cases these problems develop during the first few weeks of therapy and stop after about a week. You can minimize possible diarrhea by making sure you take Cytotec with food.

Because these side effects are usually mild to moderate and usually go away in a matter of days, most patients can continue to take Cytotec. If you have prolonged difficulty (more than 8 days), or if you have severe diarrhea, cramping and/or nausea, call your doctor.

Take Cytotec only according to the directions given by your physician.

Do not give Cytotec to anyone else. It has been prescribed for your specific condition, may not be the correct treatment for another person, and would be dangerous if the other person were pregnant.

This information sheet does not cover all possible side effects of Cytotec. This patient information leaflet does not address the side effects of your arthritis/pain medication. See your doctor if you have questions.

Keep out of reach of children.

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Research Letter

FREE

Provision of Abortion Medications Using Online Asynchronous Telemedicine Under Shield Laws in the US

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Despite the wave of state-level abortion bans following the overturn of *Roe v Wade*, recent data suggest that abortion rates have remained steady or even increased.[1] One plausible contributor is the rise of online asynchronous telemedicine abortion services—particularly those operating under shield laws, which allow US-licensed clinicians to provide abortion medications to patients in ban states with protection from legal liability.[2] To better understand usage of this care model, we analyzed 15 months of data from Aid [redacted], a nonprofit asynchronous telemedicine service that provides abortion medications to patients in all 50 states

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Methods

During the study period, Aid Access was the only organization serving all states and offering a sliding-scale fee for patients experiencing financial hardship. Patients completed an online consultation reviewed by a US-licensed clinician, and if eligible, were provided with mifepristone and misoprostol, along with instructions and remote support.

We investigated how state abortion policy, travel distance, and poverty were associated with county-level provisions. State policies were classified as protective, telemedicine ban, or near-total ban (eAppendix in Supplement 1). Travel distance was measured from the population centroid of each county to the nearest abortion clinic[4]; poverty was measured as the percentage of residents living below the federal poverty line.[5] We calculated per capita provision rates and unadjusted rate ratios for each of these structural factors. To estimate adjusted rate ratios, we fit a bayesian negative-binomial regression model with fixed effects for policy, travel distance, poverty, and broadband access; state-level random effects; and a population offset. To avoid overadjustment and interpretive ambiguity, we did not include additional aggregate demographic variables. We used R version 4.3.1. All data were fully deidentified. (Patients provided consent for the anonymized use of their data for research purposes at the time of making a request to Aid Access.) The University of Texas at Austin Institutional Review Board approved the study.

Results

Between July 1, 2023, and September 30, 2024, Aid Access provided 118 338 medication abortion pill packs to residents of 2649 US counties, of which 99 293 (84%) were in states with near-total or telemedicine bans (Figure). Unadjusted provision rates were higher in counties with more restrictive state policies, longer travel distances, greater poverty, and lower broadband access (Table). However, these structural factors were strongly correlated at the county level. The adjusted rate ratios in the Table reflect the association of each factor with provision rates, holding the other factors constant. After adjustment, provision rates were 3.12 times higher in near-total-ban states (95% posterior credible interval [CrI], 2.16-4.47), and 2.33 times higher in telemedicine-ban states (95% posterior CrI, 1.57-3.38) relative to protective states. Compared with counties within 50 miles of a clinic, provision rates were higher for counties 100 miles to 250 miles (rate ratio, 1.18; 95% posterior CrI, 1.10-1.27) and more than 250 miles (rate ratio, 1.56; 95% posterior CrI, 1.36-1.79) from a clinic. Provision rates also rose with poverty. Compared with counties with less than 5% poverty, counties with 5% to 9% poverty had 1.47 times higher provision rates (95%

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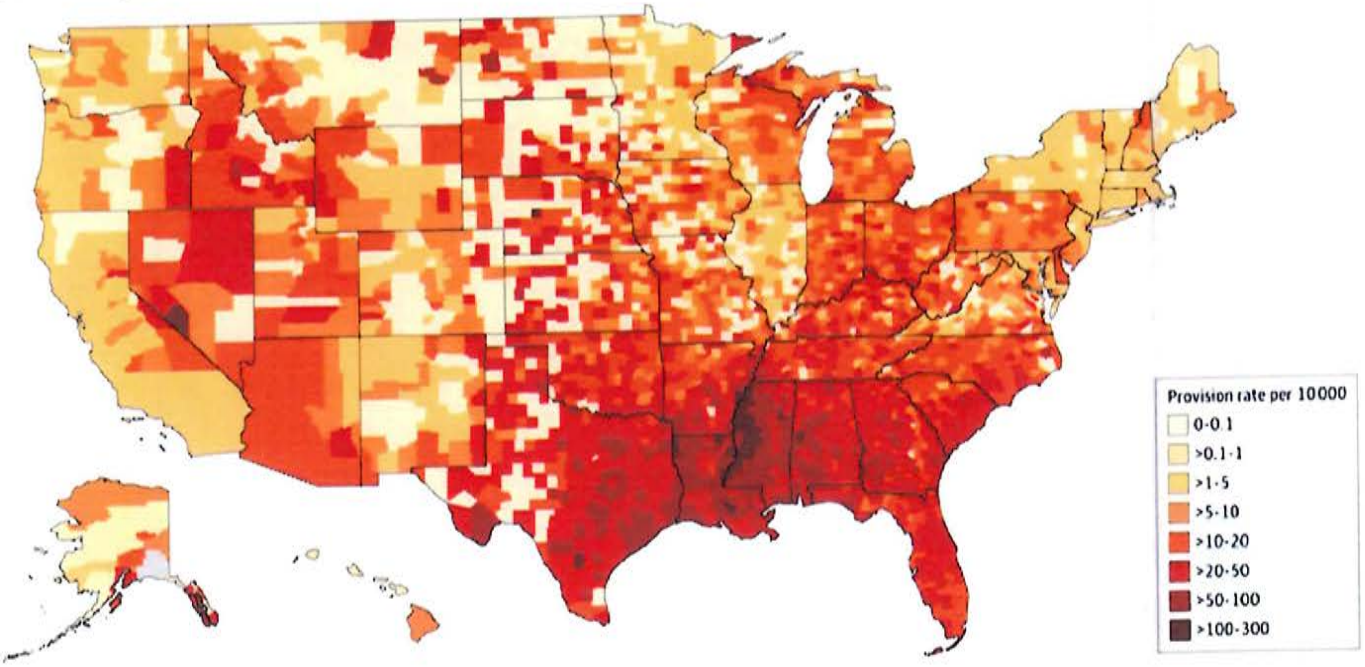
Figure. Geographic Variation in Aid Access Provision Rates of Abortion Medication via Telemedicine, July 1, 2023-September 30, 2024



County-level telemedicine abortion provision rates—defined as the number of medication abortion pill packs provided during the study period via online asynchronous telemedicine per 10 000 female residents aged 15 to 44 years—exhibit high geographic variability. The map shows provision rates across counties in the United States and the District of Columbia during the 15-month study period; darker shades indicate higher rates, with the highest concentrations in the South and Midwest, particularly in states with near-total bans.

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Table. County-Level Provision Rates and Unadjusted and Adjusted Rate Ratios for Telemedicine Abortion Provision[a]

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Variables	Provision rate per 10 000	Rate ratio	
		Unadjusted	Adjusted (95% posterior CrI)
State-level abortion policy			
Protective	5.7	1 [Reference]	1 [Reference]
Telemedicine ban	20.5	3.63	2.33 (1.57-3.38)
Near-total ban	41.3	7.31	3.12 (2.16-4.47)
Travel distance to nearest clinic, miles			
<50	10.1	1 [Reference]	1 [Reference]
50-99	15.9	1.58	1.03 (0.97-1.09)
100-250	25.6	2.53	1.18 (1.10-1.27)
>250	57.7	5.71	1.56 (1.36-1.79)
County residents living in poverty, %			
<5	5.3	1 [Reference]	1 [Reference]
5-9	10.4	1.95	1.47 (1.19-1.81)
10-20	20.3	3.8	1.63 (1.31-2.01)
>20	30.8	5.77	1.94 (1.55-2.42)
County households with ≥10 Mb/s broadband, %			
<60	19.4	1 [Reference]	1 [Reference]
≥60	17.8	0.92	1.19 (1.14-1.26)

Abbreviation: CrI, credible interval.

[a] Provision rates per 10 000 female residents aged 15 to 44 years, unadjusted rate ratios, and adjusted rate ratios were estimated from a negative binomial regression model of county-level telemedicine abortion provision, based on 118 338 abortions provided between July 1, 2023, and September 30, 2024, across 2649 US counties. The regression model includes state abortion policy, travel distance to the nearest clinic, county poverty level, broadband access, and state-level random effects, adjusting for county population via a log offset. Unadjusted rate ratios compare provision rates across categories without adjustment; adjusted rate ratios reflect associations after controlling for the other predictors in the regression model.

Discussion

Asynchronous online telemedicine abortion is widely used in the US. Provision under shield laws is strongly associated with structural barriers to in-clinic care—but even in states where abortion is protected and shield law protections are not required, telemedicine usage remains associated with distance and cost barriers. These findings underscore the public health importance of telemedicine, both as an alternative to the unsafe abortion methods that prevailed under abortion bans before *Roe v Wade*[6] and as a means of reducing access disparities.

Our analysis is limited by reliance on county-level rather than individual-level associations and by data that measure provision of abortion medications rather than completed abortions. Moreover, it does not capture the full scope of telemedicine in states without bans, where other abortion providers also operated during the study period.

Article Information

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Author Contributions: Dr Aiken had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Concept and design: All authors.

Acquisition, analysis, or interpretation of data: All authors.

Drafting of the manuscript: Aiken.

Critical review of the manuscript for important intellectual content: All authors.

Statistical analysis: Scott.

Obtained funding: Aiken.

Administrative, technical, or material support: Gomperts.

Conflict of Interest Disclosures: Dr Gomperts reported being founder and director of Aid Access. No other disclosures were reported.

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Disclaimer: All authors agree to be accountable for all aspects of the work.

Data Sharing Statement: See Supplement 2.

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