

Planned Parenthood

# **REQUEST FOR SURGERY OR SPECIAL PROCEDURE AND** ACKNOWLEDGEMENT OF RECEIPT OF NOTICE OF HEALTH INFORMATION PRIVACY PRACTICES

Before you give your consent, be sure you understand the information given below. If you have any questions, we will be happy to talk about them with you. You may ask for a copy of this form.

I understand that I must tell the staff if language interpreter services are necessary to my understanding of the written or spoken information given during my health care visits. I understand that free interpretive services may not be immediately available and Planned Parenthood may need to refer me to another health care facility to provide the services necessary for my care.

I understand that the information I will provide is true, accurate, and complete and that my healthcare choices depend on that information.

I will be given information about the test(s), treatments, service(s)/procedure(s)/ surgery to be provided, including the benefits, risks, possible problems/complications and alternate choices. I was given written patient information and/or a copy of the Planned Parenthood Client Information for Informed Consent sheet. It was reviewed with me.

I understand that with any service/procedure/surgery, there is also the possibility of side effects. I understand that I should ask questions about anything I do not understand. I understand that a clinician is available to answer any questions I may have.

No guarantee about the results from this service/procedure/surgery has been given to me. I know that it is my choice whether or not to have this service/procedure/surgery. I know that I can change my mind about receiving this service at Planned Parenthood at any time.

I understand that if tests for certain sexually transmitted infections are positive, reporting of positive results to public health agencies is required by law.

I understand that if I have an abnormal test result, the verbal or written communication I receive will include the following: an explanation and meaning of the abnormal finding and the possible consequences of not receiving additional care and/or treatment if needed.

I will be given referrals for further diagnosis or treatment if necessary. I understand that if referral is needed, I will assume responsibility for obtaining and paying for this care. I will be told how to get care in case of an emergency. If there is an unexpected complication during the service/procedure/surgery, I request and authorize the clinician and authorized Planned Parenthood staff to do whatever is necessary to preserve my health and welfare.

In the event I need more pain medication to safely continue or complete the procedure, I request and authorize Planned Parenthood staff to give me medications they believe necessary. This may include medications to reduce pain and/or anxiety. I understand every medication carries a small risk. I understand the clinician will only use medications if s/he believes it is clinically indicated.

I request that a person authorized by Planned Parenthood provide appropriate evaluation, testing, and treatment (including a birth control drug or device, if I request it) and perform the following service(s)/ procedure(s)/surgery:

- **In-Clinic Suction** used to induce a first trimester abortion, for termination of a pregnancy in the first 12 -14 weeks of gestation. A vacuum source, a vacuum curette and sometimes a sharp curette are used to confirm complete evacuation of uterine contents.
- □ In-Clinic Dilation & Evacuation (D&E) Abortion used to induce a second trimester abortion, for termination of a pregnancy after 12 - 14 weeks of gestation. A greater degree of cervical dilation is required, and suction curettage alone is inadequate. Long, heavy forceps are frequently required, as well as additional time for completion.
- **Osmotic Dilator Insertion prior to Surgical Abortion** – Short thin rods placed in the cervix (opening of uterus) to

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stretch the opening before the abortion procedure.

- □ **The Abortion Pill** Prescription medicine taken to stop pregnancy development and cause passage of uterine pregnancy up to 10 weeks gestational age, or used to prepare the cervix for dilation and evacuation procedure.
- Uterine Aspiration Removal of blood or remaining pregnancy tissue from uterus following abortion.
- □ **Treatment of Miscarriage with a Suction Procedure** Removal of remaining pregnancy tissue from uterus following an early pregnancy loss.
- □ **Treatment of Miscarriage with Abortion Pill** Prescription medicine taken to cause passage of pregnancy tissue following an early pregnancy loss.
- □ **Colposcopy** Use of microscope to look for abnormal cells on cervix (opening of uterus).
- □ Cervical Biopsy and Endocervical Sampling (ECS) Removal of small piece(s) of tissue on cervix to check for abnormalities.
- **Endometrial Biopsy** Removal of cells from lining of uterus to check for abnormalities.
- □ Vulvar Biopsy Removal of small piece of tissue from the lips of vagina to check for abnormalities.
- Cryotherapy of Cervix Freezing of top layer of cervix (opening of uterus) to treat abnormal cells.
- □ **LEEP** A small electrical wire loop used to remove abnormal tissue from the cervix.
- □ IUC Insertion Placement of □ Mirena □ Skyla □ ParaGard into the uterus to prevent pregnancy.
- □ **Contraceptive Implant Insertion** After a shot of numbing medicine, birth control device (flexible 1 <sup>1</sup>/<sub>2</sub>" rod) is placed under skin of upper arm to prevent pregnancy.
- □ **Contraceptive Implant Removal** After a shot of numbing medicine, small cut is made in skin and the birth control device is removed through it.
- Prenatal Care Healthcare provided during pregnancy.
   I understand that PPOSBC does not provide delivery services. I am being referred to \_\_\_\_\_\_ Hospital for delivery. I also understand that the health care providers at the hospital who will provide delivery services are not actin at the direction of or as agent of Planned Parenthood.
- □ **Vasectomy** A method of permanent birth control. After a shot of numbing medicine, the vas deferens are cut or blocked.
- □ **Cervical polyp removal** Removal of growth at opening of the uterus. The growth will be sent to the laboratory for testing.
- □ **Fine Needle Aspiration of Breast (FNA)** Use of a thin needle to remove cells or fluid from a lump in the breast. The cells or fluid will be sent to the laboratory for testing.
- □ **Breast Cyst Aspiration** Use of a thin needle to remove the fluid from a fluid filled lump in the breast.
- □ Treatment of Bartholin's Duct Abscess (I & D) Small cut made to infected area to drain fluid from it.
- □ Skin Biopsy Removal of a very small piece of skin to check for disease or remove the problem.
- □ Sedation
- Digoxin Injection- Digoxin is a medication used to stop the fetal heart beat before an abortion procedure.
- □ **Other:**\_\_\_\_\_

In case of emergency I give my permission for the transfer of my medical records to the Hospital providing care and, to other medical providers, if necessary. I also consent to the transfer of laboratory reports and medical records form the hospital back to Planned Parenthood. If HIV testing and education have been done, I understanding that a separate consent form for the release of such results must be signed.

PPOSBC is a teaching institution, and a person in training, under strict supervision may deliver/perform some components of my care. I have been informed and agree to such participation.

I understand that suspicions of child abuse and neglect, statutory rape, domestic violence and sexual assault are required to be reported according to state law. NOTICE TO CONSUMERS: Medical doctors are licensed and regulated by the Medical Board of California (800) 633-2333; www.mbc.ca.gov

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Physician assistants are licensed and regulated by the Physician Assistant Committee (916) 561-8780; www.pac.ca.gov

I understand that confidentiality will be maintained as described in Planned Parenthood of Orange and San Bernardino Counties' Notice of Health Information Privacy Practices. I consent to the use and disclosure of my health information as described in Notice of Health Information Privacy Practices.

**I hereby acknowledge** receipt of Planned Parenthood of Orange and San Bernardino Counties' and FPACT notice of health information privacy practices. I have had the opportunity to read the notice and I understand that someone is available to answer any questions I may have.

I witness that the patient received the above mentioned information, said it was read and understood, and had the opportunity to ask questions.

Witness signature

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CHECK HERE IF patient's GUARDIAN OR RELATIVE IS LEGALLY REQUIRED TO SIGN BELOW.

4.

Signature of any other person consenting	Date	Relationship to patient	

I witness the fact that the patient legal guardian (or person consenting on the patient's behalf) received the above mentioned information and said it was read and understood.

Witness signature

Date

D 1 /

Date

Date

3



# Information for Informed Consent USING THE ABORTION PILL

# What is the abortion pill and how do I take it?

"Abortion pill" is the popular name for using 2 medicines to end a pregnancy — mifepristone and misoprostol. Mifepristone is the first pill you will take and starts the abortion process. Pregnancy needs a hormone called progesterone to grow normally. Mifepristone blocks your body's own progesterone.

The second medicine, misoprostol, opens the cervix and makes the uterus contract. This empties the uterus and completes the process. The whole process is also called medication abortion.

There are a few different ways to take these medicines. We will talk to you about your choices.

Before you have an abortion, you need to know the most common benefits, risks, side effects, and other choices you have. We are happy to answer any questions you have.

#### What are the benefits of the abortion pill?

It is a safe and effective way to end a pregnancy.

#### How well does the abortion pill work?

It depends how far along you are in the pregnancy. Some people need to take an extra dose of misoprostol.

8 weeks or less	About 94 to 98 out of 100 times, depending on when you take the misoprostol
From 8 to 9 weeks	About 94 to 96 out of 100 times, depending on when you take the misoprostol
From 9 to 10 weeks	About 91 to 93 out of 100 times

# What are the risks of the abortion pill?

Using the abortion pill is very safe. But, there are risks with any medical procedure.

#### Risks of the abortion pill are

- The pregnancy doesn't end Sometimes the medicines do not end the pregnancy. If this happens, you can take
  more medicine or have a suction procedure to complete the abortion.
- Incomplete abortion This means some of the pregnancy may be left inside the uterus. This may lead to heavy bleeding, infection, or both. If this happens, you may need a suction procedure, other tests or treatments.
- Blood clots in the uterus Clots may cause cramping and belly pain. If this happens, you may need a suction procedure.
- Bleeding too much or too long This may require treatment with medicine, a suction procedure, or a blood transfusion.
- Infection of the uterus Most infections can be treated with medicines. But, there is a small chance that you
  may need a suction procedure. You may have to go to the hospital, or even have other surgery to treat the
  infection.
- Allergic reaction Some people are allergic to the medicines that are used.
- Death Death from medication abortion is very rare. The risk of death from childbirth is much greater.



# Information for Informed Consent USING THE ABORTION PILL

#### What are the side effects of the abortion pill?

Side effects usually do not last long. They usually need little or no treatment.

- Cramping is expected It will be the worst soon after you take the misoprostol. Milder cramps may last a day or 2 after that.
- Bleeding is expected It will be heaviest soon after you take the misoprostol. You may bleed or spot for 4 to 6 weeks after the abortion.
- Fever Having a temperature of 99-100°F is okay.
- Other It is common to have chills, diarrhea, nausea, vomiting, headache, dizziness, back pain, and tiredness.

#### Besides taking the abortion pill, what other choices do I have?

If you are pregnant, you have 3 options to think about — abortion, adoption, and parenting.

There are 2 ways to have an abortion, the abortion pill and in-clinic abortion.

We can talk about any of these options with you, and help you with whatever you decide to do.

#### What else do I need to know?

After you take the abortion pill, you must make sure the medicines worked. This can be done by having an ultrasound at the clinic. We will tell you how, when, and where to do this.

Misoprostol can cause serious birth defects if the pregnancy continues.

Having a wide range of feelings is normal. Most people feel relieved and do not regret their decision. Others may feel sadness, guilt, or regret after an abortion, just as they may after having a baby. If your mood keeps you from doing the things you usually do each day, call us. We can help or send you to someone who can.

We will also tell you other reasons to contact us.

No promise can be made about the outcome of your abortion. In the unlikely event that you need emergency medical care that cannot be provided at Planned Parenthood, you will be responsible for paying for it. This is the case even if Planned Parenthood sends you to another doctor or hospital because of a problem.

Your health is important to us. If you have any questions or concerns, please call us. We are happy to help you.

Signature of Patient (and person authorized to sign for patient w	vhen required) Date
Relationship to Patient: □ self □ parent □ legal guardian □	□ other
I witness that the patient received this information, said it was re	ead and understood, and there was an opportunity to
ask questions.	



# Information for Informed Consent USING THE ABORTION PILL

Signature of Witness

Date



# **Client Information**

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AD	or	tion	Op	ο	ns	

	Abortion Pill		In-Clinic Abortion		
How well does it work?	8 weeks or less From 8 to 9 weeks From 9 to 10 weeks *Depending on wher	About 94 to 98 out of 100 times About 94 to 96 out of 100 times About 91 to 93 out of 100 times	It almost always works - over 99% of the time.		
When can it be done?	Up to 10 weeks		Up to 24 weeks		
How does it happen?	the pregnan <ul> <li>Some need a sec</li> <li>You have a follow</li> </ul>	up to 48 hours later to pass	<ul> <li>In the clinic, your doctor or nurse will use gentle suction to remove the pregnancy.</li> <li>You will be in a recovery area until it's safe to go home, usually after 15 to 45 minutes.</li> <li>In most cases, no follow-up appointment is needed.</li> </ul>		
How long does it take?	Usually 24 hours or le several days.	ess, but it can take up to	About 10 minutes.		
How will I feel?	within 1 to 4 hours a	<ul><li>Dizziness</li><li>Back pain</li></ul>	<ul> <li>You may feel</li> <li>Mild to moderate cramping during and after the abortion. You may have cramping on and off for 1 or 2 more days.</li> </ul>		
What can I do for pain?	Pain medicine is available. Your doctor or nurse will discuss your choices with you.				
How much will I bleed? For how long?		clots is common after taking g may continue on and off for 4	Light or medium bleeding is common for 1 to 7 days. Bleeding may continue on and off for 4 to 6 weeks.		
What are the benefits?		e natural, like a miscarriage. nay be more private and you.	<ul> <li>It is over in a few minutes.</li> <li>You may have less bleeding than you would with the abortion pill.</li> <li>Clinic staff is there to support you.</li> </ul>		
What are the risks?	<ul> <li>If it doesn't work, you may need to have a suction procedure to complete the process.</li> <li>If it doesn't work, you may need to have a organs.</li> <li>If it doesn't work, you may need a suction procedure to complete the process.</li> </ul>				
	For both procedures, risks includePregnancy does not endInfectionSome of the pregnancy left in uterusAllergic reaction to medicines usedBlood clots in uterusDeathHeavy bleeding				



	Abortion Pill	In-Clinic Abortion
How much does it cost?	<ul> <li>Cost ranges from \$600 to \$750.</li> <li>State funding, private insurance and other funding sources may cover some of the costs.</li> </ul>	<ul> <li>Cost ranges from \$500 to \$3000.</li> <li>State funding, private insurance and other funding sources may cover some of the costs.</li> </ul>



# **BUCCAL MISOPROSTOL PLAN**

Patient Name: \_\_\_\_\_ Today's Date: \_\_\_\_\_

	Day/Date	Time
Mifepristone 200mg. (taken in health center)		
<b>Misoprostol 200mcg (4 tablets).</b> Put all four tablets between lower cheek and gums; leave in for 30 minutes, then swallow any remaining medication.		
For NAUSEA:		
<b>Compazine (prochlorperazine) 5mg.</b> Take <b>right before</b> Misoprostol, and then as needed every 4 hours. May cause drowsiness. Do not drive.		
For PAIN:		
<b>Ibuprofen 800mg.</b> Take 1 tab <b>right before</b> misoprostol and then every 6-8 hours as needed for pain. Do not take on an empty stomach.		
OR/AND		
<b>Tylenol Regular Strength 325mg.</b> Take 2 tabs every 4-6 hours as needed for pain.		
Follow-Up Appointment		

# Other instructions: \_\_\_\_\_

In case of an emergency after hours, call our 24- hour emergency number: Orange 714-922-4122 | San Bernardino 909-915-2076



# **Client Information**

# ULTRASOUND EXAMINATION

Before you have an ultrasound examination, be sure you understand the procedure. If you have any questions, we will be happy to talk about them with you.

Ultrasound is a procedure that helps the clinician to see the pregnancy in order to tell the age of the embryo or fetus and to look at your uterus. This is done with an instrument that sends sound waves through the tissues.

This ultrasound is being done only to determine the age of the embryo or fetus and its location and not to detect abnormalities of the pregnancy, fetus, or reproductive tract. If more studies are needed, you will be referred to an appropriate provider. There are limitations to all imaging techniques, and none is 100% accurate or reliable.

# Información para el cliente

# **EXAMEN POR ULTRASONIDO**

Antes de someterse al examen por ultrasonido (ecografía), asegúrese de que entiende el procedimiento. Si tiene dudas, con gusto se las aclararemos.

El examen por ultrasonido (ecografía) es un procedimiento que ayuda al clínico a ver el embarazo para determinar la edad del embrión o feto y observar su útero (matriz). Esto se realiza con un instrumento que emite ondas ultrasónicas a través de los tejidos.

La ecografía se efectúa únicamente para determinar la edad del embrión o feto y su ubicación, no para detectar anormalidades del embarazo, del feto o de los órganos reproductivos. Si fuera necesario efectuar otros estudios, usted sería derivada a un profesional de la salud competente. Todas las técnicas de estudio por imágenes tienen limitaciones y ninguna ofrece una exactitud del ciento por ciento.



#### You will take 2 different medicines for your abortion.

- You will take mifepristone on **DAY 1**.
- You will take misoprostol on **DAY 1 or 2 or 3**.

# <u>DAY 1</u>

#### What will I do when I come to the clinic?

You will be given 1 mifepristone pill to swallow either at the clinic.

#### **GETTING READY FOR THE MISOPROSTOL**

You will bleed and have cramps after you take the misoprostol. Plan ahead before you take it.

- Choose a time when you can be private and rest for a while after you take it.
- Plan to have someone you trust on hand to help you out.
- Buy maxi pads, pain medicine, food, and anything else you think you will need.

#### TAKING THE MISOPROSTOL

How do I take the misoprostol? You will be given 4 misoprostol pills.

- Take the anti-nausea pills, if we gave them to you, and pain medicine to prevent cramps. You can use ibuprofen.
   Do <u>NOT</u> take aspirin, because it will make you bleed more.
- Wait 30 minutes and then take the misoprostol pills according to the directions circled below.

<u>Vaginal</u>	<b>Day 1 or 2 or 3</b> (0-48 hours after taking the mifepristone)	<ul> <li>Wash your hands.</li> <li>Put 4 pills into your vagina.</li> <li>Push them in as far as they will go.</li> </ul>
<u>Sublingual</u>	<b>Day 2 or 3</b> (24-48 hours after taking the mifepristone)	<ul> <li>Put 4 pills under your tongue.</li> <li>Wait 30 minutes.</li> <li>Swallow what is left.</li> </ul>
<u>Buccal</u>	<b>Day 2 or 3</b> (24-48 hours after taking the mifepristone)	<ul> <li>Put 2 pills on one side of your mouth. Put the other 2 pills on the other side. Make sure they are between your cheek and gum.</li> <li>Wait 30 minutes.</li> <li>Swallow what is left.</li> </ul>

#### What will happen to me after I take the misoprostol?

You'll start to have strong cramps and bleeding within 1 to 4 hours after taking the misoprostol. It can last for hours. It is heaviest when the pregnancy comes out. The pregnancy is very small. You may not see it. You might see it if you



are more than 8 weeks (2 months) pregnant. At 8 weeks, the fetus is about ¼ to ½ inch long. Cramping and bleeding will slow down after it comes out.

#### What else do I need to know?

- Bleeding can be heavy. You may see large blood clots the size of a lemon.
- You may have nausea, vomiting, and diarrhea.
- You may also have mild fever, chills, dizziness, headache, back pain, and tiredness.

#### Your cramps may be strong. To feel better, you can

- Take your pain medicine.
- Put a hot water bottle or heating pad on your belly.
- Take a shower.
- Sit on the toilet.
- Have someone rub your back.

#### How will I feel after the pregnancy comes out?

**Bleeding** — It is normal to bleed. You may have little or no bleeding for a few days or weeks. Bleeding may stop and then start again. You may bleed like a normal menstrual period for 1 or 2 weeks. It should get lighter and lighter. Bleeding may continue on and off for 4 to 6 weeks. You should have your normal period again 4 to 8 weeks later.

**Cramping** — You will cramp less and less as the hours and days go by.

**Fever and chills** — You may have fever and chills the day you take the **misoprostol**. It is **<u>NOT</u>** normal to have a fever after that. Call us right away if you do. It could be a sign that you are getting an infection.

Nausea — This should go away in 1 or 2 days after you take the misoprostol.

Tiredness — You may feel tired for 1 or 2 days. You should be back to normal soon.

**Breast changes** — Tenderness should go away in a few days. You may leak a milky discharge. Wear a snug-fitting bra if you do. This should stop in 1 or 2 days.



#### Why do I need to follow-up?

Follow-up is important so we can make sure that the pregnancy ended and that you are well.

#### How do I follow-up?

You have decided to follow-up with

□ An ultrasound at the clinic.

We have given you instructions about how, when and where to follow-up. If you are unable to follow-up as planned, please contact us.

#### What else do I need to know?

#### When can I return to my normal activities?

Plan on relaxing for the rest of the day after the pregnancy comes out. Most people return to their normal activities the next day, but do **NOT** do hard work or heavy exercise for several days.

You can have sex as soon as you feel ready. You can get pregnant again within 2 weeks of the abortion, so you should start your birth control as you were instructed. We can help you if you haven't chosen a method yet.

# When will I get my next period?

When your next period will come depends on the birth control method you use. If you are not using birth control, you should have a period within 8 weeks of the abortion. If you are not using birth control and you do not get a period within 8 weeks, call us.

If you followed up with either MLPTs or an LSPT and do not get a period within 6 weeks, check a home pregnancy test, even if you are using birth control.

#### Should I use tampons or maxi pads?

Using maxi pads makes it easier to tell how much you are bleeding. You can use tampons when the heavy bleeding lets up.

# What if I am breastfeeding?

Both misoprostol and mifepristone can pass into your breast milk in small amounts after you take it. These amounts shouldn't cause any problems for you or your baby. Tell your doctor or nurse if you're breastfeeding so you can work out the best plan together.

#### Call us right away at Orange 714-922-4122 or San Bernardino 909-915-2076 if you

- Have a fever of 100.4°F or higher more than 24 hours after you've taken the misoprostol.
- Have belly pain or cramps that don't get better with pain medicine.



- Soak 2 maxi pads an hour for more than 2 hours.
- Pass blood clots larger than the size of a lemon for more than 2 hours.
- Are weak, have nausea, vomiting or diarrhea for more than 24 hours after taking misoprostol. All of these could be signs of serious infection.



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**HOW MUCH ¿CUANTO ESTOY AM I BLEEDING**? SANGRANDO? Scant amount **Cantidad muy escasa** Blood only on tissue Solo hay sangre en el papel sanitario cuando when wiped or less than se limpia, o tiene manchas que miden menos one-inch stain on maxi pad de una pulgada en una toalla sanitaria within one hour. tamaño maxi en menos de una hora. **Light amount** Poca cantidad Less than four-inch stain Manchas que miden on maxi pad within one hour. menos de 4 pulgadas en una toalla sanitaria tamaño maxi en menos de una hora. **Moderate amount Cantidad moderada** Less than six-inch stain on Manchas que miden menos de 6 pulgadas en maxi pad within one hour. una toalla sanitaria tamaño maxi en menos de una hora. Cantidad Heavy amount Saturated maxi pad within one hour. muy fuerte Una toalla sanitaria tamaño maxi completamente saturada en una hora. **Courtesy of PP Western Washington** CAPS CONSORTIUM OF ABORTION PROVIDERS

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# PROCHLORPERAZINE (GENERIC FOR COMPAZINE)

# How to use the medication:

Prochlorperazine is used to treat nausea and vomiting. Do not share this medication with others.

# Side Effects:

This medication may cause, constipation, drowsiness, dizziness, blurred vision, dry mouth, agitation, restlessness, muscle twitching, uncontrolled movements, drooling, low blood pressure, enlarged or tender breasts, increased swelling.

# **Precautions:**

# Do not take if you have a seizure disorder.

May aggravate glaucoma, cause Parkinson like symptoms or interfere with certain lab tests. Notify clinician if you have asthma, Reye's syndrome, liver or urinary problems **DO NOT TAKE IF YOU ARE ALLERGIC TO PROCHLORPERAZINE** 

# Warning:

This medication may increase your sensitivity to sunlight. Avoid prolonged sun exposure, tanning booths and sun lamps.

It may inhibit your body's ability to adjust to temperature changes. Avoid very hot or very cold temperatures.

Discontinue medication and call the clinic immediately if you develop shortness of breath, difficulty breathing, rash, itching, seizures, high fever, severe muscle stiffness, or irregular or fast heartbeat. If you are unable to breathe, dial 911.

Store at room temperature (59-86°F) away from moisture and sunlight

# KEEP MEDICATIONS OUT OF THE REACH OF CHILDREN, NEVER SHARE YOUR MEDICINES WITH OTHERS, AND USE THIS MEDICATION ONLY FOR THE INDICATION PRESCRIBE

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# Ibuprofen 800mg

# How to use the medication:

Ibuprofen has been prescribed for your pain. It is a non-steroidal anti-inflammatory drug (NSAID). Take as directed by your clinician. Do not take more than the prescribed dose. The tablets may be taken with food or milk. Take with a full glass of water.

# Side Effects:

This medication may cause stomach upset, nausea, vomiting, heartburn, gas, diarrhea or constipation.

# **Precautions:**

Do not take this medicine with other medicines that contain aspirin, ibuprofen or naproxen.

This medicine can cause ulcers and bleeding in the stomach and intestines. This bleeding can happen without warning signs and can cause death. To reduce your risk, avoid drinking alcohol or smoking cigarettes while you are taking this medicine.

You may get dizzy or drowsy while taking this medicine so use caution while driving or performing other tasks that require alertness until you know how this medicine will affect you.

# Warning:

Do not take if you are allergic to ibuprofen, aspirin, NSAIDs, or any other part if this drug, have acute or severe bronchial asthma, or liver problems.

Discontinue medication and contact the health center immediately if you develop shortness of breath, swelling of the face, lips or tongue, difficulty breathing, rash or itching. If unable to breathe, dial 911.

Store at room temperature (59-86°F) away from moisture and sunlight.

KEEP MEDICATIONS OUT OF THE REACH OF CHILDREN , NEVER SHARE YOUR MEDICINES WITH OTHERS, AND USE THIS MEDICATION ONLY FOR THE INDICATION PRESCRIBED

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# 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).

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