

PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

Mifepristone 200mg tablets¹¹

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you personally. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

In this leaflet:

1. What Mifepristone 200mg tablets is and what it is used for
2. Before you take Mifepristone 200mg tablets
3. How to take Mifepristone 200mg tablets
4. Possible side effects
5. How to store Mifepristone 200mg tablets
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1. WHAT MIFEPRISTONE 200MG TABLETS IS AND WHAT IT IS USED FOR

Mifepristone is an anti-hormone that acts by blocking the effects of progesterone, a hormone which is needed for pregnancy to continue. Mifepristone 200mg tablets can therefore cause termination of pregnancy. Mifepristone 200mg tablets can also be used to soften and open the entrance (the cervix) to the womb (uterus).

Mifepristone 200mg tablets is recommended for the following indications:

- 1) For the medical termination of a pregnancy:
 - No later than 84 days after the first day of your last period.
 - In combination with another treatment, a so-called prostaglandin analogue, that increases contraction of the womb. Generally this will be a medicine called misoprostol.
- 2) For softening and opening of the cervix before surgical termination of pregnancy during the first trimester.
- 3) As pre-treatment before giving a prostaglandin analogue (mostly misoprostol) for termination of pregnancy for medical reasons beyond 3 months gestation.

2. BEFORE YOU TAKE MIFEPRISTONE 200MG TABLETS

Do not take Mifepristone 200mg tablets

If you

- are allergic (hypersensitive) to the active substance mifepristone or any of the other ingredients of Mifepristone 200mg tablets.
- suffer from adrenal failure.
- suffer from severe asthma which cannot be adequately treated with medication.

¹ Trade names are not prequalified by WHO. This is the national medicines regulatory authority's (NMRA) responsibility. Throughout this WHOPAR the proprietary name is given as an example only.

- have hereditary porphyria (an inherited disorder of the blood).

In addition,

For termination of pregnancy up to 84 days after your last menstrual cycle:

- If your pregnancy has not been confirmed by a gynaecological examination, a biological test or an ultrasound scan.
- If the first day of your last period was more than 84 days ago (if there is any doubt, the health care provider can check the age of your pregnancy).
- If your health care provider suspects an ectopic pregnancy (the egg is implanted outside the womb).
- If you cannot use misoprostol (the prostaglandin analogue)

For softening and opening the cervix before surgical termination of pregnancy:

- If the pregnancy has not been confirmed by a biological test or an ultrasound scan.
- If your health care provider suspects an ectopic pregnancy.
- If the first day of your last period was 84 days ago and more.

For termination of pregnancy beyond 3 months pregnancy:

- - If you cannot use misoprostol (the prostaglandin analogue)

Warnings and precautions

Talk to your health care provider before using Mifepristone 200mg tablets

- if you have a heart complaint.
- if you have risk factors for heart diseases, such as high blood pressure or high blood cholesterol levels (increased fat content in your blood).
- if you suffer from asthma.
- if you suffer from an illness that may affect the clotting of your blood.
- if you have liver or kidney disease.
- if you are anaemic or malnourished.

Your health care provider will then discuss with you if you may have the treatment.

You can have prolonged and/or heavy vaginal bleeding (an average of about 9 days or more after Mifepristone 200mg tablets intake. The presence of those bleedings is not related to the success of the method.

For pregnancies that have occurred with an intrauterine contraceptive device (coil) in place, this must be removed before treatment.

Before taking Mifepristone 200mg tablets your blood may be tested for Rhesus factor. If you are Rhesus negative your health care provider will advise you of the routine treatment required.

Children and adolescents

Data on the use of mifepristone in adolescents are limited.

Other medicines and Mifepristone 200mg tablets

Tell your health care provider if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Medicines containing the following active substances may interfere with the action of Mifepristone 200mg tablets:

- Corticosteroids (used in the treatment of asthma or other inflammation treatments)
- Ketoconazole, itraconazole (used in antifungal treatment)
- Erythromycin, rifampicin (antibiotics)
- St John's Wort (natural remedy used in the treatment of mild depression)
- Phenytoin, phenobarbital, carbamazepine (used in the treatment of seizures; epilepsy)

Mifepristone 200mg tablets may interfere with the action of certain medicines, such as

- cyclosporine, tacrolimus, sirolimus, everolimus (used after organ transplantation)
- ergotamines (used for migraine headache)
- fentanyl (morphine-like medicine used to treat severe pain)
- quinidine (heart medicine)
- and some agents used in general anaesthesia.

Taking Mifepristone 200mg tablets with food and drink

Do not drink grapefruit juice when you are treated with Mifepristone 200mg tablets.

Pregnancy and breast-feeding

Failure of pregnancy termination (continuing pregnancy) after taking Mifepristone 200mg tablets alone or in combination with a prostaglandin analogue and conducted to term has been associated with increased risk of birth defects.

If a failure is diagnosed at a control visit (continuing pregnancy), and if you still agree, another method will be used to terminate your pregnancy.

Your health care provider will advise you of the options.

If you wish to continue this pregnancy, you must know that there is an unknown risk for the foetus.

In that case, a careful prenatal ultrasound monitoring with special attention to the limbs may be established.

The risk of failure of pregnancy termination increases

- if misoprostol is not administered according to its prescribing information (see section 3).
- with the duration of the pregnancy.
- with the number of pregnancies you have had before.

Avoid getting pregnant again before your next menstrual cycle after taking Mifepristone 200mg tablets.

Practise reliable contraception during this period starting immediately after termination of the pregnancy.

Because mifepristone may pass into breast milk and be taken in by your baby, stop breastfeeding once you have taken the treatment.

Driving and using machines

Mifepristone 200mg tablets may make you dizzy. Do not drive a car or operate machinery until you know how this medication affects you.

3. HOW TO TAKE MIFEPRISTONE 200MG TABLETS

Always take Mifepristone 200mg tablets exactly as your health care provider has told you. Check with your health care provider if you are not sure.

1) Medical termination of a developing intra-uterine pregnancy

- One tablet of Mifepristone 200mg tablets should be swallowed with some water in the presence of a health care provider.
- You will be able to go home after taking Mifepristone 200mg tablets once the health care provider is sure that you will not be sick. If you experience symptoms such as severe abdominal pain, fainting, fast heartbeat, fever lasting more than 4 hours after taking Mifepristone 200mg tablets, please tell your health care provider.
- You will use misoprostol 24 to 48 hours after administration of Mifepristone 200mg tablets. For further information check the patient information leaflet of the misoprostol-containing medicine.
- The pregnancy may be expelled within a few hours or during next few days after misoprostol treatment. In rare cases, the pregnancy may be expelled before you take misoprostol tablets.

In an emergency or if you are worried for any reason, you can contact or return to the hospital/clinic. You will be given the telephone number to call for emergencies or any problems.

Your health care provider may also schedule a follow-up visit within 7 to 14 days after intake of Mifepristone 200mg tablets.

After treatment you should be aware that:

- Uterine bleeding usually starts 1 to 2 days after taking the mifepristone tablet. The bleeding may last 2 or 3 weeks (on average 9 days). If the bleeding is heavy and prolonged, contact your healthcare provider immediately for an earlier appointment.
- The presence of these bleedings is not related to the success of the treatment. If pregnancy continues or expulsion is incomplete, you will be offered a surgical method for terminating your pregnancy.

2) For softening and opening the cervix before surgical termination of pregnancy

- Mifepristone 200mg tablets is taken as a single dose of one tablet containing 200 mg mifepristone. The tablet should be swallowed with some water in the presence of a health care provider.
- After mifepristone administration, you return home with an appointment 36 to 48 hours later for the surgical procedure. Your health care provider will explain the procedure to you. It is possible that you will experience bleeding after taking mifepristone, before the surgery.

In rare cases, expulsion can also occur before surgery. It is essential that you are checked to confirm that a complete evacuation has occurred and you must return to the centre for this.

- You will be given a telephone number to call for emergencies.
- You must return to the centre selected for the surgery.

3) For termination of pregnancy beyond first three months of gestation

- Mifepristone 200mg tablets is taken as a single dose of one tablet containing 200 mg mifepristone. The tablet should be swallowed with some water in the presence of a health care provider.
- You will be given an appointment for admission to treatment centre 36 to 48 hours later to receive misoprostol which may need to be given several times at regular intervals until the termination is complete (for further details check the patient information leaflet of the misoprostol-containing medicine).

Use in children and adolescents

Only limited data is available on the use of Mifepristone 200mg tablets in adolescents.

If you take more Mifepristone 200mg tablets than you should

As you will be supervised during administration of the treatment it is unlikely that you will take more Mifepristone 200mg tablets than you should.

If you forget to take Mifepristone 200mg tablets

If you forget to take any part of the treatment, it is likely that the method will not be fully effective. Talk with your health care provider if you forgot to take the treatment.

If you have any further questions on the use of this product, ask your health care provider.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Mifepristone 200mg tablets can cause side effects, although not everybody gets them

Very common (may affect more than 1 in 10 people): uterine contractions or cramping in the hours following misoprostol administration, effects related to misoprostol use such as nausea, vomiting or diarrhoea.

Common (may affect up to 1 in 10 people): heavy bleeding, infection of the uterus (endometritis and pelvic inflammatory disease), light or moderate gastrointestinal cramping.

Uncommon (may affect up to 1 in 100 people): hypersensitivity reactions, skin rashes and blood pressure fall.

Rare (may affect up to 1 in 1,000 people): headaches, malaise, vagal symptoms (hot flushes, dizziness, chills), fever, hives and skin disorders sometimes serious (erythroderma, epidermal necrolysis and erythema nodosum).

Very rare (may affect up to 1 in 10,000 people): Localised swelling of face and/or larynx which can be with urticaria, fatal or serious toxic shock syndrome caused by infection of the womb by certain bacteria, presenting with or without fever or other obvious symptoms of infection.

In a very small number of women, especially those who have had an operation on the womb or have had a baby by cesarean delivery, there is a risk that the womb may split or rupture.

Pregnancy

If the pregnancy continues and you decide to keep it, discuss this with your health care provider who may arrange careful prenatal monitoring..

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

Mifepristone 200 mg Tablets
(China Resources Zizhu Pharmaceutical
Co. Ltd), RH 052

WHOPAR part 3

5. HOW TO STORE MIFEPRISTONE 200MG TABLETS

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the box and blister after EXP.

Do not use if the box or the blister shows signs of damage.

Do not store above 30°C. Protect from light. Store in the original package.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Mifepristone 200mg tablets contains

The active ingredient is mifepristone.

The other ingredients are: colloidal silicon dioxide, corn starch, povidone, magnesium stearate, and microcrystalline cellulose.

What Mifepristone 200mg tablets looks like and content of the pack

Mifepristone 200mg tablets are yellowish, round biconvex tablets, debossed with M1 on one side. The other side is plain.

Each carton box contains 1 tablet (single dose) or 3 tablets (hospital pack) packed in a blister.

Supplier and Manufacturer

China Resources Zizhu Pharmaceutical Co., Ltd.
No. 27, Chaoyang North Road
Chaoyang District
Beijing 100024
China

For any information about this medicinal product, please contact the supplier (see above).

This leaflet was last approved in March 2017.

Detailed information on this medicine is available on the World Health Organization (WHO) web site:
<https://extranet.who.int/prequal>