

## WHO-PQ RECOMMENDED PATIENT INFORMATION LEAFLET

*This patient information leaflet focuses on uses of the medicine covered by WHO's Prequalification Team - Medicines. The recommendations for use are based on WHO guidelines and on information from stringent regulatory authorities.\**

*The medicine may be authorised for additional or different uses by national medicines regulatory authorities.*

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\* [https://extranet.who.int/prequal/sites/default/files/document\\_files/75%20SRA%20clarification\\_Feb2017\\_newtempl.pdf](https://extranet.who.int/prequal/sites/default/files/document_files/75%20SRA%20clarification_Feb2017_newtempl.pdf)

## Information for the patient

**[RH052 trade name]<sup>†</sup>**  
Mifepristone

*If you are a carer or parent looking after the person who takes this medicine, use this leaflet to give the medicine correctly and take note of the warnings and side effects.*

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have questions about the medicine, ask your health care provider.
- This medicine is for you only. Do not pass it on to others. It may harm them, even if their illness seems to be the same as yours.
- If you are concerned about any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. See section 4.

### What is in this leaflet

1. What [RH052 trade name] is and what it is used for
2. What you need to know before you take [RH052 trade name]
3. How to take [RH052 trade name]
4. Possible side effects
5. How to store [RH052 trade name]
6. Contents of the pack and other information

#### 1. What [RH052 trade name] is and what it is used for

[RH052 trade name] contains mifepristone which is an anti-hormone that acts by blocking the effects of progesterone, a hormone which is needed for pregnancy to continue. [RH052 trade name] also helps to soften the cervix (opening to the womb).

[RH052 trade name] can therefore be used with other medicines to induce abortion (termination of pregnancy), or to help prepare the body for an abortion by mechanical means (surgical abortion).

It can be used similarly to help remove the fetus if it has died in the womb and cannot be expelled naturally.

#### 2. What you need to know before you take [RH052 trade name]

##### Do not take [RH052 trade name] if:

- you are allergic to mifepristone or any other medicine required for use in combination with mifepristone, or to any of the other ingredients of [RH052 trade name] (listed in section 6)
- your pregnancy has not been properly confirmed (by an examination by a health care provider, an ultrasound scan or biological tests)
- you have, or are suspected to have, a pregnancy growing outside the womb (ectopic pregnancy)
- your adrenal gland does not work properly (adrenal failure)
- you have severe asthma that cannot be adequately treated with medication
- have inherited porphyria (a rare metabolic disorder)

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<sup>†</sup> Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

## Warnings and precautions

Talk to your health care provider before taking [RH052 trade name] if:

- you have had genital cutting or circumcision
- you have liver or kidney disease; if you have severe liver or kidney disease you should not use this medicine and your health care provider will recommend another procedure
- you are malnourished
- you have anaemia (low red blood cell count), or an illness that affects the clotting of your blood (which makes you bleed easily)
- you have been using corticosteroid medication.

If any of these apply, your health care provider will discuss with you whether [RH052 trade name] is suitable for you.

Since [RH052 trade name] must be followed by another medicine (misoprostol) to complete your treatment, you should read the product information for the other medicine as well before you start treatment with [RH052 trade name]. If you are unsure or have any questions, speak to your health care provider before you begin the treatment.

Before you receive [RH052 trade name] you will normally need to be checked by a health care provider to see how far along your pregnancy is. This might include an ultrasound scan.

If you have an intrauterine contraceptive device (coil) in place, this must be removed before treatment.

Speak to your health care provider if you have any infection in your genital area, as this should be treated before you receive [RH052 trade name]. Also speak to your health care provider at once if you think you have an infection after you have been treated with [RH052 trade name].

Before taking [RH052 trade name] 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.

***If you are taking [RH052 trade name] to terminate an ongoing pregnancy,*** your health care provider should explain the procedure to you, including how to take [RH052 trade name]. They will also give you information about possible bleeding after the procedure and how long it may last, how to look after yourself and look out for complications that may occur, and how and where to get help if you need it.

### *Children and adolescents*

There is not much information on the use of this medicine in patients under 18 years.

[RH052 trade name] should not be used in children who have not reached puberty.

## Other medicines and [RH052 trade name]

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 or increase the risk of side effects:

- corticosteroids (used in the treatment of asthma or other conditions where there is inflammation)
- ketoconazole, itraconazole (medicines used for fungus infections)
- erythromycin, rifampicin (antibiotics)
- St John's wort (natural remedy used in the treatment of mild depression)
- phenytoin, phenobarbital, carbamazepine (used in the treatment of epilepsy and seizures [fits])

Mifepristone tablets may interfere with the action of some other medicines, such as:

- cyclosporine, tacrolimus, sirolimus, everolimus (used after organ transplantation)
- ergotamine, dihydroergotamine (used for migraine headache)
- fentanyl (morphine-like medicine used to treat severe pain)

- quinidine (heart medicine)
- some medicines used in general anaesthesia.

### **Taking mifepristone with food and drink**

Do not drink grapefruit juice when you are treated with mifepristone tablets.

### **Pregnancy, breast-feeding and fertility**

#### *Pregnancy*

This medicine should not be used during pregnancy if you wish to go on and have the baby.

It is important that you take [RH052 trade name] as instructed by your health care provider. If you take [RH052 trade name] to terminate a pregnancy and the medicine does not work, your baby may be at risk of birth defects. It is not known how big the risk is.

If the medicine does not work and you decide to continue with the pregnancy, careful pre-natal monitoring and repeated ultrasound scans must be carried out in a specialised clinic. Your health care provider will talk to you about this.

You should avoid getting pregnant again before your next period after taking this medicine. To avoid becoming pregnant, you should start contraception (birth control) immediately after your health care provider tells you that the termination of the pregnancy is successful.

#### *Breastfeeding*

If you are breastfeeding, talk to your health care provider before using [RH052 trade name]. Mifepristone passes into breast milk and you should not breastfeed for one week after taking [RH052 trade name].

#### *Fertility*

[RH052 trade name] does not affect fertility. You can become pregnant again as soon as your termination is completed. You should start contraception immediately after the termination of the pregnancy is confirmed.

### **Driving and using machines**

Treatment with [RH052 trade name] can cause symptoms such as dizziness, which may increase the risks of tasks such as driving or operating machinery. Make sure you are well enough before taking on such tasks.

## **3. How to take [RH052 trade name]**

Always take [RH052 trade name] exactly as your health care provider has told you. Check with your health care provider if you are not sure.

The tablet must not be crushed, broken or chewed.

Treatment with [RH052 trade name] is followed with treatment with another medicine called misoprostol. Misoprostol acts on the womb to produce contractions and helps the cervix (the opening of the womb) to relax and widen so that the contents can be expelled. Your health care provider will tell you how to take misoprostol. For further information on misoprostol, see the patient information leaflet for misoprostol.

### **Induction of abortion (termination of pregnancy)**

Take one (1) tablet of [RH052 trade name]. The tablet should be swallowed with some water. If you vomit (throw up) shortly after taking the tablet, tell your health care provider as soon as you can.

- Then *after 24 to 48 hours*, you should take the medicine misoprostol, as directed by your health care provider.

Your health care provider may also schedule a follow-up visit within 7 to 14 days after taking [RH052 trade name] to confirm the procedure has worked and that you are well.

**After treatment** you should be aware that:

- After taking the first (mifepristone 200 mg) tablet, you will have some bleeding from your womb. Bleeding usually starts 1 to 2 days after taking the mifepristone tablet. The bleeding may last 9 to 13

- days. Your health care provider will explain how to manage the bleeding. If the bleeding is heavy and prolonged, contact your health care provider immediately for an earlier appointment.
- Bleeding does not mean the treatment has already worked. You must continue to take the tablets as instructed by your health care provider.

### **Missed abortion at less than 14 weeks of gestation**

If your pregnancy has stopped developing early on, and is not expelled naturally from the womb (missed abortion), then you may be given:

one (1) tablet of [RH052 trade name] followed after at least 24 hours by misoprostol, as directed by your health care provider.

### **Death of the baby in the womb (intrauterine foetal death) at 14 to 28 weeks of gestation**

If your baby dies in the womb and is not expelled naturally from the womb (stillbirth), then you may be given: one (1) tablet of [RH052 trade name], followed after 24 hours to 48 hours by misoprostol, as directed by your health care provider.

### **Softening and opening of the cervix before surgical termination of pregnancy during the first trimester.**

Take one (1) tablet of [RH052 trade name]. 36 to 48 hours after this, you will come back to the prescribing centre for the surgical procedure. In rare cases, expulsion can also occur before surgery. It is essential that you return to the centre to confirm that a complete evacuation has occurred.

### **If you take more [RH052 trade name] tablets than you should**

If you take too many tablets of [RH052 trade name], tell your health care provider as soon as you can.

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

## **4. Possible side effects**

Like all medicines, [RH052 trade name] can cause side effects, although not everybody gets them. Because this medicine is given with another medicine, misoprostol, side effects may also occur due to the combination of the two medicines; read the patient information leaflet for any other medicines you are given and talk to your health care provider if you have any concerns.

If you notice any of the following symptoms or side effects, **tell your health care provider immediately**:

- sudden severe pain in your belly that may indicate a tear or rupture of the womb, especially if you have had a previous caesarean section or other operation on the womb
- persistent heavy bleeding, for example soaking two sanitary pads per hour, for more than two hours
- signs of infection of the womb or toxic shock syndrome such as persistent fever with a temperature of 38°C or higher for more than 4 hours, rapid heart rate, muscle pain, confusion, vomiting and weakness, or an unpleasant smelling discharge
- persistent pain unrelieved by medication
- Severe skin rashes, especially with fever or flu-like symptoms, or swelling under the skin of the face and throat

Other side effects (contact your health care provider if any of these get serious or if you are worried):

**Very common** side effects (may affect more than 1 in 10 people):

- contractions or cramping of the womb
- feeling sick (nausea)
- being sick (vomiting)
- shivering

- fever (including temperature above 40°C)

**Common** side effects (may affect up to 1 in 10 people):

- cramping in the gut (gastrointestinal cramping)
- headache
- dizziness/fainting
- chills

**Uncommon** side effects (may affect up to 1 in 100 people):

- low blood pressure
- rash
- tiredness

**Rare** side effects (may affect up to 1 in 1,000 people):

- nettle rash, serious skin rashes with redness or blistering (erythroderma, epidermal necrolysis and erythema nodosum)
- hot flushes
- feeling generally unwell

**Very rare** side effects (may affect up to 1 in 10,000 people):

- Swelling under the skin of the face and throat, sometimes with rash (angioedema)
- effects on the heart or circulation, including heart attack (myocardial infarction), spasm of the arteries supplying the heart, severe low blood pressure
- serious or fatal toxic shock syndrome caused by infection of the womb by certain bacteria, which may occur without fever or other obvious symptoms of infection

Side effects whose **frequency has not been determined**:

- allergic reaction, potentially severe (anaphylaxis)
- back pain

**Pregnancy**

If the pregnancy continues despite taking [RH052 trade name] and you decide to keep it, the medicine can cause abnormalities (malformation) in the baby. Discuss this with your health care provider, as careful prenatal monitoring may need to be arranged.

**Reporting of side effects**

If you get a side effect, talk to your health care provider. This includes side effects not listed in this leaflet. You may also be able to report such effects directly to your national reporting system if one is available. By reporting side effects, you can help to improve the available information on this medicine.

**5. How to store [RH052 trade name]**

Keep this medicine out of the sight and reach of children.

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

Do not use this medicine after the expiry date stated on label after 'EXP'. The expiry date refers to the last day of that month.

Do not use this medicine if you notice description of the visible signs of deterioration that it is different from the description below.

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

## 6. Contents of the pack and other information

### What [RH052 trade name] contains

- The active ingredient is mifepristone.
- The other ingredients of [RH052 trade name] are colloidal silicon dioxide, corn starch, povidone, magnesium stearate, and microcrystalline cellulose.

There is too little sodium in this medicine to have any effect, even if you are on a low-sodium diet.

### What [RH052 trade name] looks like and contents of the pack

Mifepristone 200mg tablets are yellowish, round tablets. They are biconvex (rounded on top and bottom) with a flat edge. The tablets have 'M1' debossed (stamped into) one side and plain on the other side.

The tablets are presented in a white and non-transparent plastic (PVC) on aluminium foil blister cards, each containing 1 or 3 tablets. Available in boxes of 1×1 or 1×3 tablets.

### Supplier and Manufacturer

#### **Supplier**

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

#### **Manufacturer**

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For any information about this medicine, contact the local representative of the supplier.

**This leaflet was last revised in May 2025**

*Detailed information on this medicine is available on the World Health Organization (WHO) website: <https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products>*