

Excellence in rural healthcare



## Information for the user : Mifepristone 200mg tablet

Labour Ward

Lincoln County Hospital : Telephone 01522 573805  
Pilgrim Hospital : Telephone 01205 445424

[www.ulh.nhs.uk](http://www.ulh.nhs.uk)

**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.
- 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. Further information

**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 end 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:

- For use in combination with another treatment, a so-called prostaglandin analogue, that increases contraction of the womb. Generally this will be a medicine called **misoprostol**.
- For softening and opening of the cervix before use of misoprostol. As pre-treatment before giving a prostaglandin analogue (mostly misoprostol) for late intrauterine fetal death and stillbirth.

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

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 an illness that may affect the clotting of your blood, if you have liver or kidney disease or if you are anaemic or malnourished.

**For softening and opening the cervix before induction of labour for the pregnancy**

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, mitraconazole (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.

Avoid getting pregnant again before your next menstrual cycle after taking Mifepristone 200mg tablets. Practise reliable contraception during this period starting immediately after the end of pregnancy.

### **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 midwife/doctor has told you.

### **Late Intrauterine Fetal Death and Stillbirth**

One Mifepristone 200mg tablet is taken as a single dose of one tablet containing 200mg Mifepristone. The tablet should be swallowed with some water in the presence of a midwife. We appreciate this may be a difficult decision for you; please feel free to take your time. The midwives and doctors will support you if you have questions.

After Mifepristone administration, you will have a set of medical observations and if within normal range and you are happy to you may return home with an appointment 36 to 48 hours later to return for the next stage of induction of labour. The midwife will explain the procedure to you and you will be given a telephone number to call if concerns or emergency.

You will be able to go home after taking Mifepristone 200mg tablets once the midwife 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 midwife.

Misoprostol to induce labour will be administered 36 to 48 hours after the administration of Mifepristone 200mg tablets. Induction process and expectations can be discussed prior to going home if required.

The next stage is induction of labour using drugs (misoprostol) and your baby may be born within a few hours or during the next few days depending on a woman's individual bodily response.

In **rare** cases, the baby may be born before you consume misoprostol tablets.

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

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

Uterine bleeding usually starts 1 to 2 days after taking the Mifepristone tablet. If the bleeding is heavy and prolonged, contact your labour ward immediately for an earlier appointment. The presence of the bleeding is not related to the success of the treatment.

**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 caesarean delivery, there is a risk that the womb may split or rupture.

**5. FURTHER INFORMATION****What Mifepristone 200mg tablets contain**

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, biconvex tablets, legibly debossed with M1 on one side. The other side is without debossment.

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 August 2018 reference World Health Organization (WHO) web site:

<https://extranet.who.int/prequal>

If you require this information in another language, large print, audio (CD or tape) or braille, please e-mail the Patient Information team at [patient.information@ulh.nhs.uk](mailto:patient.information@ulh.nhs.uk)