

PACKAGE LEAFLET: INFORMATION FOR THE USER

Mifegyne 200 mg tablets Mifepristone

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 doctor.*
- *This medicine has been prescribed for you. 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 get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.*

In this leaflet:

1. What Mifegyne is and what it is used for
2. Before you take Mifegyne
3. How to take Mifegyne
4. Possible side effects
5. How to store Mifegyne
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1. WHAT MIFEGYNE IS AND WHAT IS IT USED FOR

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

Mifegyne is recommended for the following indications:

- 1) For the medical termination of a pregnancy:
 - no later than 63 days after the first day of your last period,
 - in combination with another treatment called prostaglandin (a substance that increases contractions of the womb) which you take 36 to 48 hours after taking Mifegyne.
- 2) For softening and opening the cervix before surgical termination of pregnancy during the first trimester.
- 3) As pre-treatment before giving prostaglandins for termination of pregnancy for medical reasons beyond 3 months gestation.
- 4) To induce labour in cases where the fetus has died in the womb and where it is not possible to use other medical treatments (prostaglandin or oxytocin).

2. BEFORE YOU TAKE MIFEGYNE

DO NOT TAKE MIFEGYNE:

• In all cases,

- if you are allergic (hypersensitive) to the active substance mifepristone or any of the other ingredients of Mifegyne,
- if you suffer from adrenal failure,
- if you suffer from severe asthma which cannot be adequately treated with medication,
- if you have hereditary porphyria.

• **In addition,**

For termination of pregnancy up to 63 days amenorrhoea:

- if your pregnancy has not been confirmed by a biological test or an ultrasound scan,
- if the first day of your last period was more than 63 days ago,
- if your doctor suspects an ectopic pregnancy (the egg is implanted outside the womb),
- if you are allergic to prostaglandins (because of the need to prescribe a prostaglandin in association with Mifegyne).

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

- if the pregnancy has not been confirmed by a biological test or ultrasound scan,
- if your doctor 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 gestation:

- if you are allergic to prostaglandins (because of the need to prescribe a prostaglandin in association with Mifegyne)

For inducing labour when the foetus has died in the womb.

If prostaglandins have to be used to complete the action of Mifegyne, refer to the product information of that medicine.

Take special care with Mifegyne

In some other circumstances the treatment may also be unsuitable for you so please tell your doctor if:

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

The doctor will then be able to discuss with you if you are able to have the treatment.

You may have prolonged and/or heavy vaginal bleeding (an average of about 12 days or more after Mifegyne intake). The presence of those bleedings is not related to the success of the method.

Taking other medicines

Medicines containing the following active substances may interfere with the action of Mifegyne:

- corticosteroids (used in the treatment of asthma or other inflammatory conditions)
- 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)

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

NSAID (non-steroidal anti-inflammatory drugs) and aspirin (acetyl salicylic acid) can decrease the efficacy of the abortive method

Taking Mifegyne with food and drink

Grape fruit juice should not be taken when you are treated with Mifegyne.

Pregnancy and breast feeding

In case of failure of the pregnancy termination, the risk for the foetus is unknown:

- if a failure is found during the check-up visit (continuing pregnancy), and if you still agree, another method will be used to complete pregnancy termination.

- If you wish to continue this pregnancy, you must know that there is a unknown risk for the fetus. In that case, a careful prenatal ultrasound monitoring will be carried out.

It is recommended that you avoid getting pregnant again before your next menstrual cycle after taking Mifegyne 200 mg tablets.

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

3. HOW TO TAKE MIFEGYNE

1) Medical termination of a developing intra-uterine pregnancy

Mifegyne is taken as a single dose of 3 tablets each containing 200mg mifepristone. The tablets should be swallowed with some water in the presence of a doctor or a member of his/her medical staff.

The prostaglandin (misoprostol 400 micrograms) is either given as tablets which should be swallowed with water or as a vaginal pessary (gemeprost 1 mg). The prostaglandin is taken as a single dose 36 – 48 hours after taking the Mifegyne.

This method involves your active participation and you should therefore be aware that:

- You need to take the second medicament (which contains prostaglandin) to ensure the treatment is effective.

- **You need to attend a check-up consultation (3rd consultation) within 14 - 21 days of taking Mifegyne in order to check that your pregnancy has been completely expelled and you are well.**

- The method of medical pregnancy termination using the combination of Mifegyne and prostaglandin is not 100 % effective. The average success rate is 95% and you may therefore require a surgical procedure to complete the treatment.

For pregnancies that have occurred with a contraceptive coil in place, the coil will be removed prior to administering Mifegyne.

The schedule below will be followed.

After the Mifegyne has been administered, you return home. Uterine bleeding usually starts 1 to 2 days after taking Mifegyne.

In rare cases, an expulsion can occur before you take the prostaglandin. It is essential that you are checked to confirm that a complete evacuation has occurred and you must return to the centre for this. Two days later the prostaglandin will be administered. You should stay at rest for 3 hours after having the prostaglandin. The pregnancy may be expelled within a few hours of prostaglandin administration or during the next few days. The bleeding lasts on average 12 days or more. In case of heavy and prolonged bleeding, you should contact the doctor immediately in order to re-schedule an earlier appointment.

You must return to the centre for the check-up consultation within 14 - 21 days after taking Mifegyne. If pregnancy continues or expulsion is incomplete, you will be offered another method for terminating the pregnancy.

It is recommended that you do not travel too far away from your prescribing centre until this date.

In an emergency or if you are worried for any reason, you can telephone your centre or go back to it before the date fixed for the next consultation. You will be given the telephone number to call for emergencies or for any problem.

Alternatively, 200 mg of mifepristone can also be used in a single oral dose. This oral dose should be followed 36 to 48 hours later, by the administration of the prostaglandin (gemeprost 1 mg) in the vagina.

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

Mifegyne 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 doctor or a member of his/her medical staff.

After Mifegyne administration, you return home with an appointment 36 to 48 hours later for the surgical procedure. Your doctor will explain the procedure to you. It is possible that you will experience bleeding after taking Mifegyne, 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. You will rest for a few hours after the surgery then return home.

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

Mifegyne is taken as a single dose of 3 tablets each containing 200mg mifepristone. The tablets should be swallowed with some water in the presence of a doctor or a member of his/her medical staff. You will be given an appointment for admission to treatment centre 36 to 48 hours later (2 days) to receive the prostaglandin which may need to be given several times at regular intervals until the termination is complete.

4) To induce labour in cases where the fetus has died in the womb.

3 tablets of Mifegyne are taken each day for two days. The tablets should be swallowed with some water.

In all cases

The use of Mifegyne requires that measures are taken to prevent Rhesus factor sensitisation (*if you are Rhesus negative*) along with the general measures taken during any pregnancy termination.

It is possible for you to become pregnant again immediately after the pregnancy termination is complete. As some effects of Mifegyne may still be present, it is recommended that you avoid getting pregnant again before your next menstrual period after taking Mifegyne.

If you take more Mifegyne than you should

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

If you forget to take Mifegyne

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

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Mifegyne can cause side effects, although not everybody gets them.

Very common (occur among more than 1 in 10 patients): uterine contractions or cramping in the hours following prostaglandin intake, effects related to prostaglandin use such as nausea, vomiting or diarrhoea.

Common (occur among more than 1 in 100 patients but less than 1 in 10 patients): heavy bleeding, infection following abortion, light or moderate gastro intestinal cramping.

Uncommon (occur among more than 1 in 1000 patients but less than 1 in 100 patients): skin rashes and fall in blood pressure have been observed.

Rare (occur among more than 1 in 10 000 patients but less than 1 in 1000 patients): headaches, malaise, vaginal symptoms (hot flushes, dizziness, chills), fever, hives and skin disorders sometimes serious (erythroderma, epidermal necrolysis and erythema nodosum) have also been reported.

Very rare (occur among less than 1 in 10000 patients): cases of fatal toxic shock caused by infection by *Clostridium sordellii*, endometritis presenting 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.

5. HOW TO STORE MIFEGYNE

Keep out of reach and out of sight of children.

Do not use after the expiry date indicated on the box.

Do not use if the box or the blisters show signs of damage.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Mifegyne contains

The active ingredient is mifepristone.

The other ingredients are: anhydrous colloidal silica, maize starch, povidone, magnesium stearate, microcrystalline cellulose.

What MIFEGYNE looks like and contents of the pack.

Mifegyne is available as yellow biconvex tablet containing 200 mg of active ingredient.

The tablets are presented in a blister put in a carton box.

Marketing Authorisation Holder

EXELGYN- 216 Boulevard Saint Germain 75007 Paris - France

Manufacturer

Mifegyne is manufactured by Macors – 89000 Auxerre – France.

**This medicinal product is authorised in the Member States of the EEA under the following name:
Mifegyne.**

This leaflet was last approved in March 2011