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Mifegyne®

MIFEPRISTONE

Mifegyne 200 mg tablets

PACKAGE LEAFLET: INFORMATION FOR THE USER

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 any further questions, ask your doctor.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

1. WHAT MIFEGYNE IS AND WHAT IT IS USED FOR

Mifegyne tablets contain mifepristone which 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 to be used:
1) For the medical termination of a pregnancy:
   - no later than 63 days after the first day of your last menstrual cycle,
   - in combination with a second medicine, a prostaglandin (a substance that triggers contraction of the womb and softens the cervix), which you take 36 to 48 hours after taking Mifegyne.
2) For softening and opening of 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 foetus has died in the womb and where it is not possible to use other medical treatments (prostaglandin or oxytocin).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE MIFEGYNE

DO NOT TAKE MIFEGYNE

• In all cases,
- if you are allergic to mifepristone or any of the other ingredients of this medicine (listed in section 6),
- 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 after your last menstrual cycle:
- if your pregnancy has not been confirmed by a biological test or an ultrasound scan,
- if the first day of your last menstrual cycle was more than 63 days ago,
- if your doctor suspects an ectopic pregnancy (the egg is implanted outside the womb),
- if you cannot take the selected 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 ultrasound scan,
- if your doctor suspects an ectopic pregnancy,
- if the first day of your last menstrual cycle was 84 days ago or more.

For termination of pregnancy beyond 3 months pregnancy:
- if you cannot take the selected prostaglandin analogue.

Warning and precautions

Talk to your doctor before taking Mifegyne
- if you have liver or kidney disease,
- if you suffer from anaemia or malnutrition
- if you have cardiovascular disease (heart or circulatory disease),
- if you are at increased risk of cardiovascular disease. Risk factors include being aged over 35 years and a cigarette smoker or having high blood pressure, high blood cholesterol levels or diabetes,
- if you have an illness that affects the clotting of your blood,
- if you suffer from asthma.

If you use a contraceptive coil it must be removed before you take Mifegyne.

Before taking Mifegyne your blood will be tested for Rhesus factor. If you are Rhesus negative your doctor will advise you of the routine treatment required.

Serious skin reactions including toxic epidermal necrolysis and acute generalized exanthematous pustulosis have been reported in association with Mifegyne treatment. Stop using Mifegyne and seek medical attention immediately if you notice any of the symptoms described in section 4. If you get a serious skin reaction you should not use mifepristone again in the future.

Other medicines and Mifegyne

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

In particular tell your doctor if you are taking the following:
- 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)
- non-steroidal anti-inflammatory drugs (NSAIDs) such as acetyl salicylic acid or diclofenac.

Mifegyne with food and drink

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

Pregnancy, breast feeding and fertility

Pregnancy

Failure of pregnancy termination (continuing pregnancy) after taking Mifegyne alone or in combination with prostaglandin and conducted to term has been associated with birth defects. The risk of failure increases:
- If the prostaglandin is not administered according to their medication prescribing information (see section 3)
- With the duration of the pregnancy
- With the number of pregnancies you have had before.

If termination of pregnancy fails after taking this medicine or combination of medicines there is an unknown risk to the foetus. If you decide to continue with the pregnancy, careful pre-natal monitoring and repeated ultrasound examinations, with a special attention to the limbs, in a specialised clinic must be carried out. Your doctor will advise further.

If you decide to continue with the termination of the pregnancy another method will be used. Your doctor will advise you of the options.

Breastfeeding

If you are breastfeeding, talk to your doctor before using this medicine. Do not breastfeed while taking Mifegyne as this medicine is passed into breast milk.

Fertility

This medicine 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 by your doctor.

Driving and using machines

Dizziness can occur as a side effect related to the abortion process. Take special care when driving or using machines after taking this medicine until you know how Mifegyne affects you.

3. HOW TO TAKE MIFEGYNE

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

1) Medical termination of a developing intra-uterine pregnancy (MToP)

Termination of pregnancy up to 49 days after your last menstrual cycle

Dosage in adults
- 3 tablets to be taken orally.

Taking the tablet
- Swallow the tablets whole with a glass of water in the presence of a doctor or a member of his/her medical staff
- Take the prostaglandin analogue, 36 – 48 hours after Mifegyne. The prostaglandin is either given as tablets which should be swallowed with water (misoprostol 400 micrograms) or as a vaginal pessary (gemeprost 1 mg)
- If you vomit within 45 minutes after taking the mifepristone tablets, talk to your doctor immediately. You will need to take the tablets again.

Termination of pregnancy 50 – 63 days after your last menstrual cycle

Dosage in adults
3 tablets to be taken orally.

Taking the tablet
- Swallow the tablets whole with a glass of water in the presence of a doctor or a member of his/her medical staff
- Take the prostaglandin analogue, 36 – 48 hours after Mifegyne. The prostaglandin is a vaginal pessary (gemeprost 1 mg)
- If you vomit within 45 minutes after taking the mifepristone tablets, talk to your doctor immediately. You will need to take the tablets again.

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 schedule for the medical termination of pregnancy will be as follows:
1) At the prescribing centre you will be given Mifegyne, which must be taken orally
2) 36 – 48 hours after this the prostaglandin analogue will be administered. You should stay at rest for 3 hours after having the prostaglandin analogue
3) The embryo may be expelled within a few hours of taking the prostaglandin analogue or during the next few days. You will have vaginal bleeding which will last for an average of 12 days after taking Mifegyne, and the flow will become lighter as time continues
4) **You must return to the centre within 14 - 21 days of taking Mifegyne, for a follow-up consultation to make sure the expulsion is complete.**

Contact your prescribing centre immediately:
- **if you have vaginal bleeding for longer than 12 days and/or if it is very heavy (e.g. you need more than 2 sanitary pads per hour for 2 hours)**
- **if you have severe abdominal pain**
- **if you have fever or if you are feeling cold and shivering.**

Other important point to remember:
- Vaginal bleeding does not mean the expulsion has been completed.

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.

If pregnancy continues or expulsion is incomplete, your doctor will advise you of the options for completion of the pregnancy termination.

It is recommended that you do not travel too far away from your prescribing centre until the follow-up consultation is done.

In case of emergency or if you have any questions, telephone or visit your prescribing centre. You do not have to wait for your follow-up appointment.

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

Dosage in adults
- 1 tablet to be taken orally

Taking the tablet
- Swallow the tablet whole with a glass of water
- If you vomit within 45 minutes after taking the mifepristone tablet, talk to your doctor immediately. You will need to take another tablet.

The schedule for the medical termination of pregnancy will be as follows:
1) At the prescribing centre you will be given Mifegyne, which must be taken orally
2) 36 to 48 hours after this you will come back to the prescribing centre 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 return to the centre to confirm that a complete evacuation has occurred.

You must return to the centre selected for the surgery.

In case of emergency or if you have any questions, telephone or visit your prescribing centre. You do not have to wait for your follow-up appointment.

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

Dosage in adults
- 3 tablets to be taken orally

Taking the tablet
- Swallow the tablets whole with a glass of water
- 36 – 48 hours after this medicine take the prostaglandin analogue, which may be repeated several times at regular intervals until the termination is complete.
- If you vomit within 45 minutes after taking the mifepristone tablets, talk to your doctor immediately. You will need to take the tablets again.

4) For inducing labour when pregnancy has been interrupted (intra-uterine foetal death).

Dosage in adults
- 3 tablets to be taken orally each day for two days

Taking the tablet
- Swallow the tablets whole with a glass of water
- If you vomit within 45 minutes after taking the mifepristone tablets, talk to your doctor immediately. You will need to take the tablets again**.**

Use in adolescents

Only limited data is available on the use of Mifegyne in adolescents.

If you take more Mifegyne than you should

If you take too many tablets, contact your doctor immediately or go to the nearest hospital casualty department.

The doctor will give you the exact amount of Mifegyne; it is therefore unlikely that you will take too many tablets. Taking too many tablets may cause symptoms of adrenal failure. Signs of acute intoxication may require specialist treatment including the administration of dexamethasone.

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 Mifegyne or the part of treatment prescribed.

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

4. POSSIBLE SIDE EFFECTS

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

Serious side effects:
- Allergic reaction. Skin rash, localised swelling of face and/or larynx which can be with urticaria
- Reddish patches on the trunk, the patches are target-like macules or circular, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (toxic epidermal necrolysis, frequency: rare).
- A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever. The symptoms usually appear at the initiation of treatment (acute generalised exanthematous pustulosis, frequency: not known).

Other serious side effects:
- Cases of serious or fatal toxic or septic shock. Fever with aching muscles, rapid heart rate, dizziness, diarrhoea, vomiting or feeling weak. This side effect may occur if you do not take the second medicine, the misoprostol tablet, orally.

If you experience any of these side effects contact your doctor IMMEDIATELY or go to your nearest hospital casualty department.

Other side effects

Very common (may affect more than 1 in 10 people):
- uterine contractions or cramping
- diarrhoea
- feeling sick (nausea), or being sick (vomiting)

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

Uncommon (may affect up to 1 in 100 people):
- blood pressure fall

Rare (may affect up to 1 in 1000 people):
- fever
- headaches
- generally feeling unwell or tired
- vagal symptoms (hot flushes, dizziness, chills)
- hives and skin disorders which can be serious
- Uterine rupture following prostaglandin administration within the second and third trimester of pregnancy, particularly in multiparous women or in women with a caesarean section scar.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:
United Kingdom
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE MIFEGYNE

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

This medicine does not require any special temperature storage conditions. Store in the original package in order to protect from light.

Do not use this medicine after the expiry date, which is stated on the carton after “EXP”. The expiry date refers to the last day of that month.

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

Do not throw away any medicines via wastewater. Ask your pharmacist 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 Mifegyne contains

The active ingredient is mifepristone.

One tablet of Mifegyne contains 200 mg 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, with a diameter of 11 mm with “167 B” engraved on one side.

Mifegyne is available in pack sizes of 1, 3 x 1, 15 x 1 or 30 x 1 tablets in PVC/aluminium perforated unit dose blister packs.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder:
EXELGYN
216 boulevard Saint-Germain
75007 Paris
France

Manufacturer:
Laboratoires Macors
22 rue des Caillottes
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 2025.

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