Package leaflet: Information for the user

Mifepristone Linepharma 200 mg tablet
mifepristone

Read all of this leaflet carefully before you start using 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 or pharmacist.
- 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.

What is in this leaflet:

1. What Mifepristone Linepharma is and what it is used for

Mifepristone Linepharma is an anti-hormone that acts by blocking the effects of progesterone, a hormone which is needed for pregnancy to continue. Mifepristone Linepharma can therefore cause termination of pregnancy.

Mifepristone Linepharma is recommended 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 contraction of the womb) which you take 36 to 48 hours after taking Mifepristone Linepharma.

2. What you need to know before you take Mifepristone Linepharma

Do not take Mifepristone Linepharma

- if you are allergic (hypersensitive) to mifepristone or any of the other ingredients of this medicine (listed in section 6)
- if you suffer from chronic adrenal failure,
- if you suffer from asthma uncontrolled by treatment,
- if you have hereditary porphyria,
- 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 (9 weeks) ago,
- if your doctor suspects an ectopic pregnancy (the egg is implanted outside the womb),
- because of the need to prescribe a prostaglandin in association with Mifepristone, you must not take this treatment if you are allergic to prostaglandins.

Warnings and precautions
Serious skin reactions including toxic epidermal necrolysis and acute generalized exanthematous pustulosis have been reported in association with Mifepristone Linepharma treatment. 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.

Take special care with Mifepristone Linepharma
In some other circumstances the treatment may also be unsuitable to you so please tell your doctor if:

- you have a heart complaint,
- a 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,
- you have an infection

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

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

Other medicines and Mifepristone Linepharma

Tell your doctor 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; epilepsia)
- non-steroidal anti-inflammatory drugs (NSAIDs) such as acetyl salicylic acid or diclofenac

Taking Mifepristone Linepharma with food and drink:

- grape fruit juice should not be taken when you are treated with Mifepristone Linepharma.

This method requires the involvement and you should therefore be aware of the requirements of the method:

- The necessity to combine treatment with prostaglandin to be administered at a second visit.
- The need for a follow up visit within 14 to 21days after intake of Mifepristone Linepharma to check that abortion is complete.
- The non-negligible risk of failure of the method which may require termination by another method, in rare case surgery may be necessary.

Pregnancy, breast-feeding and fertility

If you are pregnant:
There is little information on the risks to the unborn baby. If the pregnancy continues and you decide to keep it, discuss this with your doctor who will arrange careful pre-natal monitoring and ultrasound examinations.

If you are breast-feeding:
Because Mifepristone Linepharma may pass into breast milk and be taken in by your baby, you should stop breast feeding once you have taken the treatment.

Fertility:
Animal studies with mifepristone do not indicate direct or indirect harmful effects with respect to fertility.

It is recommended that you avoid getting pregnant again during your next menstrual period after taking Mifepristone Linepharma.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

No studies on the effect on the ability to drive and use machines have been reported.

3. How to use Mifepristone Linepharma

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

Mifepristone Linepharma is for oral use.

The method of administration is 200 mg of mifepristone (1 tablet) should be taken, followed 36 to 48 hours later by the administration of a prostaglandin analogue (1 pessary containing 1 mg of gemeprost placed in the vagina).

If you are taking certain other medicines, you may need a higher dose of mifepristone.
It is important that you tell your doctor if you are taking any other medicines. See section 2 “Other medicines and Mifepristone Linepharma”.

The Mifepristone Linepharma tablet should be swallowed with some water in the presence of a doctor or a member of his/her medical staff.

In the case of a pregnancy occurring with an intra-uterine device in place, this device must be removed.

The expulsion may take place before prostaglandin administration (in about 3% of cases). This does not preclude the follow up visit to check that the abortion is complete.

After Mifepristone Linepharma has been administered, you will return home. Uterine bleeding usually starts 1 to 2 days after taking Mifepristone Linepharma.

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 and 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 in average 12 days or more. In case of heavy or prolonged bleeding, you should contact your doctor immediately in order to re-schedule an earlier appointment.

You must return to the center for a check-up consultation within 14 to 21 days after taking Mifepristone Linepharma. 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 center until this date.
In an emergency or if you are worried for any reason, you can telephone your center 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.

The use of Mifepristone Linepharma 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 Mifepristone Linepharma may still be present, it is recommended that you avoid getting pregnant again before your next menstrual period after taking Mifepristone Linepharma.

Use in children

No data are available for women under 18 years.

If you take more Mifepristone Linepharma than you should

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

If you forget to take Mifepristone Linepharma

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

Contact your doctor or go to the nearest hospital department immediately if you experience any of the following symptoms:

- Heavy vaginal bleeding (frequency: common). Also see section 2 “Warnings and precaution”
- Infections: cases of fatal toxic shock caused by infection by *Clostridium sordellii* endometritis. It may cause symptoms such as fever with aching muscles, rapid heart rate, dizziness, diarrhoea, vomiting or feeling weak. It can also occur without fever or other obvious symptoms of infection (frequency: rare or very rare)
- Serious allergic reactions (angioedema and anaphylaxis) with swelling of the face, tongue or throat; difficulty swallowing; hives and breathing difficulties (frequency: rare or very rare)
- Cardiovascular accidents: heart attack, heart rhythm disorder (frequency: rare or very rare)
- Steep fall in blood pressure caused by loss of a large amount of blood (hemorrhagic shock) (frequency: uncommon)
- 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 or very 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 side effects that may occur:
The following side effects have been observed:
Very common side effects:(may affect more than 1 in 10 people)

- headache
- vaginal bleeding

- effects related to prostaglandin use such nausea, vomiting, diarrhoea, dizziness, abdominal discomfort, abdominal pain, uterine spasm, fatigue and chill/fever
- uterine contractions or cramping in the hours following prostaglandin intake.

Common side effects: (may affect up to 1 in 10 people)
- prolonged bleeding after the abortion
- spotting
- severe bleeding
- endometritis (inflammation of the womb)
- breast tenderness
- fainting
- cramping

Uncommon side effects: (may affect up to 1 in 100 people)
- salpingitis (infection in the fallopian tubes)
- infection
- hypotension

Rare (may affect up to 1 in 1,000 people) and very rare (may affect up to 1 in 10,000 people) side effects:
- ectopic pregnancy
- bilateral adnexal mass (increase size in fallopian tubes)
- intrauterine adhesion, uterine rupture, hematosalpynx (bleeding in the fallopian tubes)
- ovarian cyst rupture
- breast abcess
- hydatiform mole, trophoblastic tumor, elevated alpha fetoprotein, elevated carcinoembryogenic antigen, amniotic band syndrome, uteroplacental apoplexia
- urticarial reaction, periorbital edema
- bronchospasm, asthma
- abnormal liver function tests
- hepatic failure
- gastric bleeding
- epilepsy
- tinnitus (ringing in the ear)
- mania
- superficial thrombophlebitis
- thrombotic thrombocytopenic purpura (coagulation disorder)
- thrombocytopenia
- induced systemic lupus erythematous
- renal failure
- muscular spasm
- ophtalmoplegia
- erythema nodosum
- vagal symptoms (hot flushes, skin rashes/itching,)
- malaise

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 uterus or womb may rupture during a further pregnancy.

Reporting of side effects

If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet.
You can also report side effects directly via the 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 Mifepristone Linepharma

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

Keep the blister in the outer carton in order to protect from light.

Do not use Mifepristone Linepharma 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 throw away any medicine 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. Contents of the pack and other information

What Mifepristone Linepharma contains

- The active substance is mifepristone. Each tablet contains 200 milligrams of mifepristone.
- The other ingredients are maize starch, povidone, cellulose microcrystalline, silica colloidal anhydrous, magnesium stearate.

What Mifepristone Linepharma looks like and contents of the pack
White to off-white, round tablet, diameter 11 mm, with MF debossed on one side of the tablet.
PVC/PVDC/Aluminum blister of 1 tablet and 30 tablets (hospital pack).

Marketing Authorisation Holder and Manufacturer

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Manufacturer

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This medicinal product is authorised in the Member States of the EEA under the following names:
France: MIFFEE® 200 mg comprimé
United Kingdom: Mifepristone Linepharma 200 mg tablet
Island: Mifepristone Linepharma 200 mg tafla
Sweden : Mifepristone Linepharma 200 mg tablett

Spain : Mifepristona Linepharma 200 mg comprimidos

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Other sources of information
Detailed information on this medicine is available on the website of of the Medicines and Healthcare Products Regulatory Agency (MHRA) of United kingdom : www.mhra.gov.uk.