PATIENT INFORMATION LEAFLET

Ask your health care provider to fill in the next lines.

Name of your health care provider:

Phone number of your health care provider:

Name of the medical practitioner handling emergencies:

Phone number of the medical practitioner handling emergencies:

SCHEDULING STATUS: S4

MIFEGYNE® 200 mg tablets

Mifepristone

Sugar free

Read all of this leaflet carefully before you start taking MIFEGYNE®

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- MIFEGYNE® has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What MIFEGYNE® is and what is used for
2. What you need to know before you take MIFEGYNE®
3. How to take MIFEGYNE®
4. Possible side effects
5. How to store MIFEGYNE®

6. Contents of the pack and other information

1. What MIFEGYNE® is and what it is used for

MIFEGYNE® contains 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.

MIFEGYNE® is used in the following situations:

1) Medical alternative to surgical pregnancy termination according to the pregnancy date in combination with another treatment called prostaglandin.
2) For softening and opening of the cervix before surgical pregnancy termination.
3) For use in combination with prostaglandins for termination of pregnancy during the second trimester.
4) To induce labour in cases where the foetus has died in the womb.

MIFEGYNE® will not be administered if there is doubt as to the existence or age of the pregnancy. Your prescribing doctor should in this case perform an ultrasound scan and/or measure the HCG (a hormone indicating pregnancy) before administration.

2. What you need to know before you take MIFEGYNE®

Do not take MIFEGYNE®:

- If you are hypersensitive (allergic) to mifepristone or to any of the other ingredients of MIFEGYNE® (listed in section 6).
- If you suffer from chronic adrenal failure (also called Addison's disease, characterised by tiredness, weakness, dizziness, low blood pressure, weight loss, stomach pain or feeling sick).
- If you suffer from severe asthma that does not get better with your usual steroid treatment, or if you have long-term lung problems, often called chronic obstructive airways disease, such as chronic bronchitis or emphysema.

- If you have porphyria (a rare blood-related condition, often causing stomach pain, weakness, vomiting, sensitivity to sunlight or dark urine).
- 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 56 days ago.
- If your doctor suspects an ectopic pregnancy (the egg is implanted outside of the womb).
- If you have an unremoved intra-uterine contraceptive device.
- If you are on long term corticosteroid therapy.
- If you have a bleeding disorder or are using any anticoagulants (used to help prevent blood clots)
- Because of the need to prescribe a prostaglandin in association with MIFEGYNE®, you must not take this treatment if you are allergic to prostaglandins.

Warnings and precautions

Serious skin reactions including toxic epidermal necrolysis and acute generalised exanthematous pustulosis have been reported in association with MIFEGYNE®. 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 MIFEGYNE® again in the future.

Talk to your doctor before taking MIFEGYNE®:

In some other circumstances, the treatment may also be unsuitable to you unless decided otherwise by your doctor. Please tell the doctor:

- If you suffer from or have had cardiovascular problems such as angina (chest pain), Raynaud's syndrome (circulatory problems in the limbs), cardiac rhythm problems, cardiac insufficiency, severe high blood pressure.
- If you have liver failure or kidney disease.
- If you suffer from malnutrition or anaemia.
- If you take on a regular basis medicines of any kind and in particular nonsteroidal anti-inflammatory agents (NSAIDs) including aspirin.

- If you suffer from asthma.
- If you suffer from an illness that may affect the clotting of your blood.
- If you are older than 35 years of age and are smoking.
- If you previously had a caesarean section or have experience one or more previous childbirths.

Medical termination of your pregnancy involves your active participation, and you should therefore be aware that:

- On your 2nd visit you need to take the second medicine prescribed to you (which contains prostaglandin) to ensure the treatment is effective.
- You need to attend a check-up consultation (3rd consultation) within 10 – 14 days of taking MIFEGYNE® in order to check that your pregnancy has been completely expelled.
- The method of medical pregnancy termination using the combination of MIFEGYNE® and prostaglandin is not 100 % effective. You may therefore require a surgical procedure to complete the treatment.

If you become pregnant with an intra-uterine device (IUD) in place, the IUD must be removed prior to taking MIFEGYNE®.

In some cases, the pregnancy may be expelled before you take the prostaglandin treatment. It is essential that you return to the hospital/clinic to confirm that a complete pregnancy termination has occurred.

After treatment, you should be aware that:
You can 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. If the bleeding is heavy and prolonged, contact the doctor immediately for an earlier appointment. It is important that you keep the follow-up appointment to check that your pregnancy has been completely expelled and you are well, as you will not be able to judge for yourself if the treatment has been successful.

If pregnancy continues or expulsion is incomplete, you will be offered a surgical method for terminating the pregnancy.

It is recommended that you do not travel too far away from your prescribing centre until your pregnancy has been completely expelled. 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. Keep this number on the top of this leaflet.

Uterine pain may be experienced, more often during the first few hours after administration. Painkillers may be required. Nulliparous women (women who have never given birth) and those with a history of dysmenorrhoea (painful menstrual cycles) are more likely to require narcotic analgesia (strong pain medicine).

Cases of serious bacterial infections which presented with atypical features, including cases of toxic shock and fatal septic shock have been reported following the use of MIFEGYNE® and a prostaglandin analogue.
However, no causal relationship between these events and the use of MIFEGYNE® and a prostaglandin analogue has been established.

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.

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 reliable contraception be used to avoid getting pregnant again before next menstrual period after taking MIFEGYNE®.

Children and adolescents

Do not give MIFEGYNE® to women and children under the age of 18 years, as no data are available.

Other medicines and MIFEGYNE®

Always tell your health care provider if you are taking any other medicine (This includes all complementary or traditional medicines).

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

- Ketoconazole, itraconazole (antifungal medicines used to treat fungal infections).
- Erythromycin (antibiotics used to treat bacterial infections).
- Rifampicin (used to treat tuberculosis [TB]).
- Corticosteroids, such as dexamethasone (used to treat inflammation in your body).
- St John's wort (natural medicine used to treat mild depression).
- Phenytoin, phenobarbital (phenobarbitone), carbamazepine (used to treat seizures [fits] and epilepsy).

As the efficacy of treatment could be affected, the use of NSAID's, including aspirin, should be avoided until pregnancy termination is complete. For termination of pregnancy of up to 63 days gestation, NSAID's should not be given at least until the follow-up visit 8 to 12 days after mifepristone administration.

A mandatory follow-up visit must take place within a period of 10 to 14 days after administration of MIFEGYNE® to verify by the appropriate means the efficacy and safety of the product.

MIFEGYNE® with food and drink

Do not eat grapefruit or drink grapefruit juice with MIFEGYNE®.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

In case of failure of the discontinuation of pregnancy, the risk to the unborn baby is unknown. If the pregnancy continues and you decide to keep the baby, discuss this with your doctor who will arrange careful

prenatal monitoring and ultrasound of the baby, special attention to the arms and legs will be performed.

MIFEGYNE® may pass into breast milk and be ingested by your baby, you should therefore stop breastfeeding your baby once you have taken MIFEGYNE®.

MIFEGYNE® does not affect fertility, and you can become pregnant again as soon as your termination is completed.

It is recommended that you avoid getting pregnant again during your next menstrual period after taking MIFEGYNE®. Reliable contraception should be used.

Driving and using machines

MIFEGYNE® may cause dizziness. It is not always possible to predict to what extent MIFEGYNE® may interfere with your daily activities. Do not drive a vehicle or operate machinery until you know how MIFEGYNE® affects you.

3. How to take MIFEGYNE®

Do not share medicines prescribed for you with any other person.

Always take MIFEGYNE® exactly as your doctor has instructed you. You

should check with your doctor or pharmacist if you are unsure.

1) Medical alternative to surgical pregnancy termination of intra-uterine pregnancy of up to 56 days after the first day of the last menstrual period and/or ultrasound scan, in combination with a prostaglandin analogue:

You will be given 3 tablets of MIFEGYNE® to swallow with some water.

You will be given a prostaglandin analogue to be taken orally at home 36 to 48 hours later.

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

You will be given 3 tablets of MIFEGYNE ® to swallow with some water.

Not later than 48 hours later, you will return to the clinic for a surgical procedure.

3) For use in combination with a prostaglandin analogue for termination of pregnancy between 13 and 20 weeks gestation:

You will be given 3 tablets of MIFEGYNE® to swallow with some water.

You will be given an appointment to return to the clinic after 36 to 48 hours, to be given a prostaglandin which administration may be repeated until the
termination has been completed.

4) To induce labour in cases where the foetus has died in the womb: You will be given 3 tablets of MIFEGYNE® to swallow with some water for two consecutive days.

Your doctor will tell you how long your treatment with MIFEGYNE® will last. If you have the impression that the effect of MIFEGYNE® is too strong or too weak, tell your doctor or pharmacist.

If you take more MIFEGYNE® than you should

In the event of an overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

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.

4. Possible side effects

MIFEGYNE® can have side effects.

Not all side effects reported for MIFEGYNE® are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking MIFEGYNE®, please consult your health care provider for advice.

If any of the following happens, stop taking MIFEGYNE® and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to MIFEGYNE®. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- heavy vaginal bleeding (see 'Warnings and precautions');
- infections: cases of septic shock caused by infection. 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;
- 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)

- 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).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- uterine bleeding, -pain or cramping;
- dizziness, headache;
- abdominal pain, nausea (feeling sick), vomiting (being sick), diarrhoea, stomach cramps.

Less frequent side effects:

- hypotension (low blood pressure);
- fever, chills, hot flushes;
- generally feeling unwell.

Side effects occurring with an unknown frequency:

- increases in urea and creatine;
- increase in hepatic enzymes causing abnormal liver function tests;
- hypoglycaemia (low blood sugar).

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 uterus or womb may rupture during a further pregnancy.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of MIFEGYNE®.

5. How to store MIFEGYNE®

- Store at or below 25 ºC.
- Protect from light.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the blister strip or carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What MIFEGYNE® contains

The active ingredient is mifepristone.

Each tablet contains 200 mg mifepristone.

The inactive ingredients are: colloidal silica (anhydrous), maize starch, povidone, microcrystalline cellulose and magnesium stearate.

What MIFEGYNE® looks like and contents of the pack

Cylindrical, biconvex, light-yellow tablets, about 11 mm in diameter with an identification code on one face (167B).

A carton containing 3 tablets, which are packed into a thick white (polyvinyl chloride acetochloride) sheet sealed onto a thick aluminium foil printed on one side.

Pack size: 3 tablets.

Holder of certificate of registration

Medi Challenge (Pty) Ltd.

493 De Jonge Street

Elardus Park

Pretoria

0181

Tel: 011 462 5491

This leaflet was last revised

Date of registration: 06 August 2001

Date of revision: 24 July 2026

Registration number

34/21.12/0328

Access to corresponding Professional Information:

Available online at: https://pi-pil-repository.sahpra.org.za/