SCHEDULING STATUS: S4

MEDIPRIST 200 mg tablets
Mifepristone
Sugar free

Read all of this leaflet carefully before you start taking MEDIPRIST 200 mg
- 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.
- MEDIPRIST 200 mg 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 MEDIPRIST 200 mg is and what it is used for
MEDIPRIST 200 mg is an anti-hormone that acts by blocking the effects of progesterone, a hormone which is needed for pregnancy to continue. MEDIPRIST 200 mg can therefore cause termination of pregnancy.

MEDIPRIST 200 mg is used for:
1) The medical termination of a pregnancy
- no later than 63 days after the first day of your last period and/or ultrasound scan,
- in combination with another treatment called prostaglandin (a substance that increases contraction of the womb) which you take 36 to 48 hours after taking MEDIPRIST 200 mg.

2) For softening and opening the cervix before surgical termination of pregnancy during the first trimester.
3) For use in combination with 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).

MEDIPRIST 200 mg 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 MEDIPRIST 200 mg
Do not take MEDIPRIST 200 mg:
- if you are hypersensitive (allergic) to mifepristone or any of the other ingredients of MEDIPRIST 200 mg (listed in section 6).
- if you suffer from chronic adrenal failure.
- if you suffer from severe asthmatic disease where it is necessary to take steroids (e.g. asthma uncontrolled by treatment) or chronic obstructive airways disease.
- 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 the first day of your last period was 84 days ago and more (for softening and opening of the cervix prior to surgical termination of pregnancy).
- 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 MEDIPRIST 200 mg, you must not take this treatment if you are allergic to prostaglandins.
- if you suffer from haemorrhagic (bleeding) disorders and are treated with anticoagulants.
- if you have an unremoved intra-uterine contraceptive device.
- if you are on long term corticosteroid therapy.

Warnings and precautions
Serious skin reactions including toxic epidermal necrolysis and acute generalised exanthematous pustulosis have been reported in association with MEDIPRIST 200 mg. 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 MEDIPRIST 200 mg:
In some other circumstances, the treatment may also be unsuitable to you so please tell your doctor:
- if you suffer from chest pain or have a prosthetic heart valve
- 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 asthma
- if you suffer from an illness that may affect the clotting of your blood or anaemia
- if you have liver or kidney disease
- if you are malnourished
- if you have an infection
- 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.

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

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 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 MEDIPRIST 200 mg in order to check that your pregnancy has been completely expelled.
- The method of medical pregnancy termination using the combination of MEDIPRIST 200 mg 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 administering MEDIPRIST 200 mg.

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 MEDIPRIST 200 mg 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.

The use of MEDIPRIST 200 mg 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 MEDIPRIST 200 mg may still be present, it is recommended that reliable contraception be used to avoid getting pregnant again before next menstrual period after taking MEDIPRIST 200 mg.

Use in children
No data are available for women under 18 years.

Other medicines and MEDIPRIST 200 mg
Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

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 (antibiotics)
- rifampicin (used in the treatment of tuberculosis)
- St John's Wort (natural remedy used in the treatment of mild depression)
- phenytoin, phenobarbital, carbamazepine (used in the treatment of seizures and epilepsy)
- non-steroidal anti-inflammatory drugs (NSAIDs) such as acetyl salicylic acid (aspirin) or diclofenac

For termination of pregnancy of up to 63 days development, NSAIDs should not be given at least until the follow-up visit 8 to 12 days after MEDIPRIST 200 mg administration.

A mandatory follow-up visit must take place within a period of 10 to 14 days after administration of MEDIPRIST 200 mg to verify by the appropriate means the efficacy and safety.

MEDIPRIST 200 mg with food and drink
MEDIPRIST 200 mg may be taken with or without food. Do not drink grapefruit juice together with the MEDIPRIST 200 mg tablet.

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 MEDIPRIST 200 mg.

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 it, 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.

If you are breastfeeding:
Because MEDIPRIST 200 mg may pass into breast milk and be ingested by your baby, you should stop breastfeeding your baby once you have taken the treatment.

Fertility:
It is recommended that you avoid getting pregnant again during your next menstrual period after taking MEDIPRIST 200 mg. Reliable contraception should be used.

Driving and using machines
MEDIPRIST 200 mg may make you dizzy.

It is not always possible to predict to what extent MEDIPRIST 200 mg may interfere with your daily activities. You should ensure that you do not engage in driving a vehicle or operating machinery until you are aware of the measure to which MEDIPRIST 200 mg affects you.

3. How to take MEDIPRIST 200 mg
Do not share medicines prescribed for you with any other person.

Always take MEDIPRIST 200 mg exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

MEDIPRIST 200 mg is for oral use.

The method of administration is 200 mg of mifepristone (1 tablet) that 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).

The dose of 200 mg should not be exceeded.

The MEDIPRIST 200 mg tablet should be swallowed with some water in the presence of a doctor or a member of his/her medical staff.

If you are taking certain other medicines, you may need a higher dose of MEDIPRIST 200 mg. It is important that you tell your doctor if you are taking any other medicines. See section 2 “Other medicines and MEDIPRIST 200 mg”.

If you take more MEDIPRIST 200 mg 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 MEDIPRIST 200 mg
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
MEDIPRIST 200 mg can have side effects.

Not all side effects reported for MEDIPRIST 200 mg are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking MEDIPRIST 200 mg, please consult your health care provider for advice.

If any of the following happens, stop taking MEDIPRIST 200 mg and tell your doctor immediately or go to the casualty department at your nearest hospital:
- swelling of the hands, feet, ankles, face, lips, 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 MEDIPRIST 200 mg. 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 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
- myocardial infarction: heart attack, irregular heart rhythm
- steep fall in blood pressure caused by loss of a large amount of blood (haemorrhagic shock)
- 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:
- headache, dizziness
- vaginal bleeding
- effects related to prostaglandin use such nausea, vomiting, diarrhoea, dizziness, abdominal discomfort, abdominal pain, uterine spasm, fatigue and chill/fever
- prolonged bleeding after the abortion
- spotting
- severe bleeding
- endometritis (inflammation of the womb)
- breast tenderness

- uterine contractions or cramping
- fainting

Less frequent side effects:
- vagal symptoms (hot flushes, skin rashes/itching)
- salpingitis (infection in the fallopian tubes)
- ectopic pregnancy (the egg is implanted outside the womb)
- bilateral adnexal mass (increase size in fallopian tubes)
- intrauterine adhesion, uterine rupture, haematosalpynx (bleeding in the fallopian tubes)
- ovarian cyst rupture
- breast abscess
- bleeding, abnormal growths and cancer in the uterus, and birth defects
- anaphylaxis, skin hives, swelling of the eyes
- low blood pressure (hypotension)
- difficulty breathing, asthma
- abnormal liver function tests
- liver failure
- gastric bleeding
- epilepsy
- tinnitus (ringing in the ear)
- mania
- blood clots
- thrombotic thrombocytopenic purpura (coagulation disorder)
- deficiency of platelets in the blood (thrombocytopenia)
- induced systemic lupus erythematous
- renal failure
- muscular spasm
- paralysis of the muscle of the eye (ophthalmoplegia)
- erythema nodosum (a painful disorder characterised by tender bumps (nodules) under the skin)
- elevated alpha-feto protein, elevated carcinoembryogenic antigen
- hepatorenal failure
- malaise (a general feeling of being ill or having no energy)

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, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of MEDIPRIST 200 mg.

5. How to store MEDIPRIST 200 mg
Store at or below 30 °C.
Keep the blister in the outer carton in order to protect from light.
Store all medicines out of the reach of children.

Do not use MEDIPRIST 200 mg after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.
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. Contents of the pack and other information
What MEDIPRIST 200 mg contains
The active substance is 200 mg mifepristone.

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

What MEDIPRIST 200 mg looks like and contents of the pack
White to off-white, round tablet, biconvex, diameter 11 mm, with MF debossed on one side of the tablet.

Transparent, colourless PVC-PVDC/ Aluminium blister of 1 tablet.
Pack sizes with 1 tablet and 30 tablets (as hospital pack) are provided in an outer cardboard carton.
Not all pack sizes may be marketed.

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