

Mifepristone Linepharma 200 mg Tablet

Each tablet contains mifepristone 200 mg

Consumer Medicine Information

This medication is for use in termination of pregnancy for medical reasons beyond the first trimester. For medical termination of pregnancy up to 63 days gestation, a different product should be used (MS-2 Step (mifepristone and misoprostol)). It is important that all patients receiving this medication are followed up by a medical practitioner to ensure the medication has been effective. Even if no adverse events have occurred all patients must receive follow up after taking mifepristone.

What is in this leaflet

This leaflet answers some common questions about Mifepristone Linepharma 200 mg tablet. It does not contain all the available information. It does not take the place of talking to your doctor.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given Mifepristone Linepharma 200 mg tablet against the expected benefits it will have for you.

If you have any concerns about being given this medicine, ask your doctor.

Keep this leaflet.

You may need to read it again.

What Mifepristone Linepharma 200 mg tablet is used for

Mifepristone Linepharma is an anti-hormone. It acts by blocking the effects of progesterone, a hormone which is needed for pregnancy to continue.

Mifepristone Linepharma can therefore be used to terminate a pregnancy.

Mifepristone Linepharma is recommended for:

The medical termination of a pregnancy beyond the first trimester (the first three months). Mifepristone Linepharma is used in combination with a second medication called a prostaglandin analogue.

Ask your doctor if you have any questions about why Mifepristone Linepharma 200 mg tablet has been prescribed for you.

This medicine is available only with a doctor's prescription, and will be given to you under the care of an appropriately trained doctor. The required prostaglandin analogue will be administered in a hospital setting.

Before you are given Mifepristone Linepharma 200 mg tablet

When you must not be given it

You should not be given Mifepristone Linepharma 200 mg tablet if:

- you are pregnant and wish to carry your pregnancy to term
- you are unable to access emergency medical care after taking this medication until the medical termination is complete
- your pregnancy and its duration have not been confirmed by an ultrasound or biological test such as urine or serum HCG.
- you have any allergies to mifepristone or any of the other ingredients listed at the end of this leaflet
- you suffer from chronic adrenal failure
- you suffer from severe disease where it is necessary to take steroids (e.g. asthma uncontrolled by treatment)
- you have known or suspected hypocoagulation diseases

- you are on anticoagulant therapy
- you are allergic to prostaglandins. This is because of the need to use a prostaglandin analogue in combination with Mifepristone Linepharma.

You should not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If this medicine is used after the expiry date it may not work as well.

If you are under 18 years of age, you should only take Mifepristone Linepharma if advised to do so by your doctor.

There is limited information on the use of Mifepristone Linepharma in adolescents under 18 years of age.

If you are not sure whether you should be given this medicine, talk to your doctor.

Your doctor will give you more information about what to expect with medical abortion, the risks and side effects, when you need to seek advice or help, and contact numbers for 24 hour assistance.

Before you take Mifepristone Linepharma

Tell your doctor if you have allergies to any other medicines, foods preservatives or dyes.

Tell your doctor if you are a smoker.

Tell your doctor if you have or have had any of the following medical conditions:

- kidney problems
- liver problems
- malnutrition
- problems with your adrenal glands
- heart or cardiovascular disease
- anaemia
- blood disorders which lead to difficulty in clotting
- if you are taking anticoagulants
- if you are taking corticosteroids including inhaled corticosteroids for the treatment of asthma
- if you have an intra-uterine device (IUD) in place

If you have not told your doctor about any of the above, tell him/her before you take Mifepristone Linepharma 200 mg tablet.

Serious skin reactions including toxic epidermal necrolysis and acute generalized exanthematous pustulosis have been reported in association with mifepristone treatment. Stop using the Mifepristone Linepharma 200 mg tablet and seek medical attention immediately if you notice any of the symptoms described under the 'Side Effects' section. If you get a serious skin reaction you should not use mifepristone again in the future.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you

buy without a prescription from your pharmacy, supermarket, health food shop, naturopath, herbalist or internet.

Some medicines and Mifepristone Linepharma 200 mg tablet may interfere with each other. These include:

- corticosteroids including inhaled corticosteroids for the treatment of asthma
- ketoconazole or itraconazole, medicines used to treat fungal infections
- erythromycin or rifampicin, antibiotics for treating infections
- St John's Wort, a natural remedy used to treat mild depression
- phenytoin, phenobarbitone, carbamazepine, medicines used to treat epilepsy

These medicines may be affected by Mifepristone Linepharma 200 mg tablet, or may affect how well it works. You may need to be given different amounts of your medicines, or you may need to be given different medicines.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while being treated with Mifepristone Linepharma 200 mg tablet.

Grapefruit juice should not be taken when you are treated with Mifepristone Linepharma 200 mg tablet.

How Mifepristone Linepharma 200 mg tablet is given

How much to take

Your doctor will tell you how many tablets you need to take and when to take them.

The usual dose of Mifepristone Linepharma is 200 mg (one tablet). You will then receive a prostaglandin analogue to complete the termination of pregnancy.

It is recommended that Mifepristone Linepharma 200 mg tablet should be taken on an empty stomach - 2 hours before or 2 hours after a meal.

How to take Mifepristone Linepharma 200 mg tablet

Mifepristone Linepharma 200 mg tablet should be swallowed with water

It is very important that you follow any instructions your doctor has given you following administration of Mifepristone Linepharma.

The completion of your pregnancy termination will take place in a hospital environment. 36-48 hours after taking Mifepristone Linepharma you will be given the prostaglandin analogue. You may require several doses of the prostaglandin before completion of the termination occurs.

It is very important that you have follow up with your doctor after you take Mifepristone Linepharma to ensure that the termination was complete because incomplete termination will increase the risk of serious infection or bleeding.

It is recommended that you do not travel away from home during the time that you are bleeding so that you can visit your doctor, clinic or hospital if necessary.

In case of heavy and prolonged bleeding, you should contact your doctor, clinic or hospital immediately to get advice and care.

Very occasionally you may begin to bleed heavily or miscarry the pregnancy before the planned administration of the prostaglandin. If you are worried this may be occurring you must follow the instructions given to you by your doctor or seek urgent medical care.

If you are given too much (overdose)

Mifepristone Linepharma 200 mg is available as a single tablet pack and it is given to you by your doctor. An overdose is not likely to occur. Ask your doctor if you have any concerns.

While you are being given Mifepristone Linepharma 200 mg tablet

Things you must do

If you are pregnant

In some cases treatment with Mifepristone Linepharma may not result in a complete termination of pregnancy and you may require another method, such as surgery, to complete the termination.

If treatment with Mifepristone Linepharma does not work or you change your mind after taking it and wish to keep your pregnancy, it is not known if Mifepristone Linepharma can cause harm to your baby.

If you are Rhesus negative, the use of Mifepristone Linepharma requires that your doctor will take measures to prevent Rhesus factor sensitization, along with the general measures taken during any pregnancy termination.

If you are breastfeeding

Mifepristone Linepharma should not be taken if you are breast-feeding.

If you are taking other medicines

If you are about to be started on any new medicines, remind your doctor or pharmacist that you have recently been given Mifepristone Linepharma 200 mg tablet.

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

Tell any other doctors, dentists, and pharmacists who treat you that you have recently been given this medicine, as it may interact with other medicines or anaesthetics they may use.

Side effects

Tell your doctor or nurse as soon as possible if you do not feel well while you are being given Mifepristone Linepharma 200 mg tablet.

Do not be alarmed by the following list of side effects, you may not experience any of them.

Tell your doctor if you notice any of the following and they worry you:

- headache
- vaginal bleeding which may be heavy or prolonged
- spotting

- cramps
- breast tenderness
- fainting
- hot flushes, skin rashes or itching
- side effects that may also be related to prostaglandin analogues such as nausea, vomiting, diarrhoea, dizziness, abdominal discomfort, abdominal pain, cramps, fatigue and chills and/or fever.

Tell your doctor if you notice anything that is making you feel generally unwell.

Skin Reaction

Serious skin reactions include reddish circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes are rare and can be preceded by fever and flu-like symptoms. A red, scaly widespread rash with bumps under the skin and blisters accompanied by fever may appear at the initiation of treatment.

Bleeding

Contact your doctor if you are concerned about bleeding after taking Mifepristone Linepharma or following discharge from hospital. Contact your doctor immediately if you find you have very heavy bleeding and have soaked more than 2 pads over 2 hours.

Infection

Serious infections are very rare in a medical termination of pregnancy but can be potentially life threatening. If you have symptoms of ongoing abdominal pain, or feeling unwell, or feeling weak, with or without a fever, you should contact your doctor without delay.

Other side effects not listed above may also occur in some people.

After being given Mifepristone Linepharma 200 mg tablet

It is very important that you follow any instructions your doctor has given you and keep any follow up appointments following administration of Mifepristone Linepharma.

Storage

Mifepristone Linepharma will be stored by your doctor or pharmacist under the recommended conditions. It should be kept in a cool, dry place where the temperature stays below 30 degrees C. Store Mifepristone Linepharma in the original packaging.

Keep Mifepristone Linepharma where children cannot reach it.

Mifepristone Linepharma should not be used after the expiry date printed on the pack. If this medicine is used after the expiry date it may not work as well.

Disposal

Any Mifepristone Linepharma which is not used will be disposed of in a safe manner by your doctor or pharmacist.

Using contraceptives

It is possible for you to become pregnant again immediately after the pregnancy termination is completed. 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.

Product description

What it looks like

Mifepristone Linepharma 200 mg tablets are white to off-white, round tablets, with MF embossed on one side of the tablet. Each tablet contains 200 mg of mifepristone. Mifepristone Linepharma 200 mg is in a blister pack of one tablet.

Ingredients

Mifepristone Linepharma contains the active ingredient mifepristone plus maize starch, povidone, microcrystalline cellulose, colloidal anhydrous silica and magnesium stearate.

The tablets do not contain gluten, lactose, tartrazine or any azo dyes.

Supplier

Mifepristone Linepharma 200 mg tablet is supplied in Australia by:

MS Health Pty Ltd
Suite 60, 278 Church Street,
Richmond, VIC, Australia, 3121

MS Health After Care line:
1300 515 883 (24 hours)

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