

Mifepristone Linepharma 200 mg Tablet

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the [full CMI](#). Read before using this medicine.

1. Why am I using Mifepristone Linepharma?

Mifepristone Linepharma contains the active ingredient mifepristone. Mifepristone Linepharma is used to terminate a pregnancy for medical reasons beyond the first trimester. Mifepristone Linepharma is used in combination with a second medicine called a prostaglandin analogue.

For more information, see Section [1. Why am I using Mifepristone Linepharma 200mg Tablet?](#) in the full CMI.

2. What should I know before I use Mifepristone Linepharma?

Do not use it if you have ever had an allergic reaction to mifepristone or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section [2. What should I know before I use Mifepristone Linepharma?](#) in the full CMI?

3. What if I am taking other medicines?

Some medicines may interfere with Mifepristone Linepharma and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Mifepristone Linepharma?

Mifepristone Linepharma should be swallowed with water. 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 to complete the termination of pregnancy.

More instructions can be found in Section [4. How do I use Mifepristone Linepharma?](#) in the full CMI.

5. What should I know while using Mifepristone Linepharma?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Mifepristone Linepharma.• It is important to have a follow up with your doctor after you take Mifepristone Linepharma to ensure that termination was complete.
Things you should not do	<ul style="list-style-type: none">• Do not take grapefruit juice when you are treated with Mifepristone Linepharma.• Do not travel away from home during the time that you are bleeding so that you can visit your doctor if necessary.
Driving or using machines	Be careful before you drive or use any machines or tools until you know how Mifepristone Linepharma affects you.
Drinking alcohol	Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none">• Mifepristone Linepharma will be stored by your doctor or pharmacist under the recommended conditions. It should be kept in a cool and dry place where the temperature stays below 30°C.• Keep Mifepristone Linepharma where children cannot reach it.

For more information, see Section [5. What should I know while using Mifepristone Linepharma?](#) in the full CMI.

6. Are there any side effects?

The common side effects include headache, dizziness, nausea, vomiting, diarrhoea, gastric discomfort, abdominal pain, spotting breast tenderness, cramping, breast tenderness, fatigue, fever / chills and fainting. Serious side effects include serious skin reactions, prolonged heavy vaginal bleeding, infections that can be potentially life threatening and ongoing abdominal pain.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

WARNING: 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 very important that all patients receiving this medicine are followed up by a medical practitioner, preferably the prescriber, to ensure that the medicine has been effective. Even if no adverse events have occurred all patients must receive follow-up after taking Mifepristone Linepharma.

Mifepristone Linepharma 200 mg Tablet

Active ingredient: *mifepristone*

Consumer Medicine Information (CMI)

This leaflet provides important information about Mifepristone Linepharma. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Mifepristone Linepharma.**

Where to find information in this leaflet:

- [1. Why am I using Mifepristone Linepharma?](#)
- [2. What should I know before I use Mifepristone Linepharma?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Mifepristone Linepharma?](#)
- [5. What should I know while using Mifepristone Linepharma?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Mifepristone Linepharma?

Mifepristone Linepharma contains the active ingredient mifepristone. Mifepristone 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 beyond the first trimester (the first three months). It is used in combination with a second medicine called a prostaglandin analogue.

Ask your doctor if you have any questions about why Mifepristone Linepharma 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.

2. What should I know before I use Mifepristone Linepharma?

Warnings

Do not use Mifepristone Linepharma if:

- you are allergic to mifepristone, or any of the ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include:
 - Reddish circular patches on the trunk
 - Skin peeling
 - Ulcers of mouth, throat, nose, genitals, and eyes
- Always check the ingredients to make sure you can use this medicine.
- you are unable to access emergency medical care after taking this medicine until the medical termination is complete
 - your pregnancy has not been confirmed by an ultrasound scan or biological test such as urine or serum HCG
 - you are pregnant and wish to carry your pregnancy to term
 - 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.

If you are under 18 years of age, you should only take mifepristone 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 use 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.

Check with your doctor if you:

- have any other medical conditions such as:
 - 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.

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 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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Do not use Mifepristone Linepharma if:

- your pregnancy has not been confirmed by a pregnancy test or an ultrasound scan
- you are pregnant and wish to carry your pregnancy to term.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Mifepristone Linepharma should not be taken if you are breast-feeding.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket, health food shop, naturopath, herbalist or internet.

Some medicines may interfere with Mifepristone Linepharma and affect how it works. 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 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.

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

4. How do I use Mifepristone Linepharma ?

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.

When to take

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

How to take

- Mifepristone Linepharma 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 prostaglandin before completion of the termination occurs.

If you use too much Mifepristone Linepharma

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.

5. What should I know while using Mifepristone Linepharma?

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.

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.

- In case of heavy and prolonged bleeding, you should contact your doctor or clinic immediately to get advice and care.
- 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.
- Tell your doctor if you are a smoker.

Call your doctor straight away:

- 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.
- Remind any doctor, dentist or pharmacist you visit that you are using Mifepristone Linepharma as it may interact with other medicines or anaesthetics they may use.

Things you should not do

- 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 or clinic if necessary.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Mifepristone Linepharma affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Mifepristone Linepharma will be stored by your doctor or pharmacist under the recommended conditions.
- Store below 30°C.
- Store in the original packaging.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

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

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Gastrointestinal related <ul style="list-style-type: none">• Nausea*• Vomiting*• Diarrhoea*• Abdominal discomfort*• Abdominal pain* Head related <ul style="list-style-type: none">• Fainting• Dizziness*• Headache Skin related <ul style="list-style-type: none">• Hot flushes• Skin rashes or itching General body related <ul style="list-style-type: none">• Chills and /or fever*• Fatigue*	Speak to your doctor if you have any of these less serious side effects and they worry you.

<p>Pregnancy related</p> <ul style="list-style-type: none"> • Uterine contractions or cramping • Vaginal bleeding which may be heavy or prolonged • Spotting • Cramps • Breast tenderness <p>* side effects that may also be related to prostaglandin analogues</p>	
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Serious side effects

Serious side effects	What to do
<p>Skin related</p> <ul style="list-style-type: none"> • 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. <p>Bleeding related</p> <ul style="list-style-type: none"> • 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. <p>Infection related</p> <ul style="list-style-type: none"> • 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. 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the

Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Mifepristone Linepharma contains

Active ingredient (main ingredient)	mifepristone
Other ingredients (inactive ingredients)	colloidal anhydrous silica magnesium stearate maize starch microcrystalline cellulose povidone
Potential allergens	No

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

Do not take this medicine if you are allergic to any of these ingredients.

What Mifepristone Linepharma looks like

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

Australian registration number: AUST R 175671

Who distributes Mifepristone Linepharma

Mifepristone Linepharma is supplied in Australia by:

MS Health Pty Ltd

Ground Floor East,

678 Victoria Street,

Richmond, VIC, Australia, 3121.

Ph: 1300 515 883

Licensed from Linepharma International Limited (UK).

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