

MS-2 Step

Mifepristone Linepharma

200 mg Tablet Pack

Each tablet contains mifepristone 200 mg

Consumer Medicine Information

It is very important that all patients receiving this medication are followed up by a medical practitioner, preferably the prescriber, to ensure that the medication has been effective. Even if no adverse events have occurred all patients must receive follow-up 14 to 21 days after taking mifepristone.

MS-2 Step is a composite pack product containing Mifepristone Linepharma 200 mg tablet (this medicine in the green box) and GyMiso[®] misoprostol 200 microgram tablets.

Mifepristone Linepharma = mifepristone

GyMiso[®] = misoprostol

What is in this leaflet

This leaflet answers some common questions about mifepristone, contained within the **MS-2 Step** pack. 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 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 the mifepristone tablet is used for

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

Mifepristone can therefore be used to terminate a pregnancy.

It is given in combination with another medicine called misoprostol a prostaglandin analogue.

Both medicines are contained within the **MS-2 Step** pack, and they are recommended for the termination of pregnancy up to 63 days after your last menstrual period.

Ask your doctor if you have any questions about why MS-2 Step has been prescribed for you.

The medicines in **MS-2 Step** are available only with a doctor's prescription.

Before you are given the mifepristone tablet

When you must not be given it

You should not be given the mifepristone tablet if:

- you are unable to access to emergency medical care in the next 14 days

- your doctor suspects an ectopic pregnancy (the egg is implanted outside the womb)
- you are using an intrauterine contraceptive device. It should be removed first.
- your pregnancy has not been confirmed by a pregnancy test or an ultrasound scan
- the first day of your last period was more than 63 days ago, unless tests have been done to confirm the age of the pregnancy is no more than 63 days
- you are pregnant and wish to carry your pregnancy to term
- 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.

You should not use this medicine after the expiry date printed on the Mifepristone Linepharma 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 if advised to do so by your doctor. There is limited information on the use of mifepristone 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 the mifepristone tablet

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
- asthma
- epilepsy
- porphyria
- 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), as this needs to be removed.

If you have not told your doctor about any of the above, tell him/her before you take the mifepristone tablet contained in the MS-2 Step pack.

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 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, 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.

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

How the mifepristone 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 is 200 mg (one tablet) in the green box. Your doctor will advise you about taking misoprostol tablets, usually 36 to 48 hours later.

It is necessary to take the mifepristone tablet first and then, 36 to 48 hours later, take the misoprostol tablets. This must be done in this order for the medicines to work.

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

How to take the mifepristone tablet

The mifepristone tablet should be swallowed with water.

Vaginal bleeding usually starts 1 to 2 days after taking the mifepristone tablet.

36 to 48 hours after taking the mifepristone tablet you need to take misoprostol tablets as directed by your doctor or given to you by medical staff. After you take misoprostol tablets, you should stay at home and rest for 3 hours. Some women may be at a clinic for this part of the treatment. Vaginal bleeding will usually occur and the pregnancy may be expelled within a few hours of taking misoprostol or during the next few days. The bleeding lasts on average for 10 to 16 days and may be heavy.

It is very important that you have follow up with your doctor 14 to 21 days after you take mifepristone, 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 or clinic if necessary.

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

In a few cases, a termination can occur after you take mifepristone but before you take misoprostol. It is essential that you are checked to confirm that a complete termination has occurred. If this occurs, you should contact your doctor immediately in order to schedule an appointment.

If you forget to take your dose of misoprostol

Contact your doctor immediately if you forget to take the dose of misoprostol tablets in the purple box, and it is greater than 48 hours after you have taken mifepristone tablet.

If you are given too much (overdose)

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

While you are being given MS-2 Step

Things you must do

If you are pregnant

In some cases treatment with *MS-2 Step* may not result in a termination of pregnancy. **You must keep all of your clinic appointments so that your progress can be checked. This is very important.**

If treatment with *MS-2 Step* does not work, a termination can be arranged using another method.

If treatment with *MS-2 Step* does not work and you wish to keep your pregnancy, it is not known if mifepristone can cause harm to your baby. It is believed, though, misoprostol can cause harm to your baby. You need to tell your doctor or nurse about *MS-2 Step* so that

they can carefully monitor your pregnancy.

If you are Rhesus negative, the use of *MS-2 Step* 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 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 *MS-2 Step*.

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 the medicines in *MS-2 Step*.

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 misoprostol 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.

Bleeding

Vaginal bleeding usually starts a few hours after taking misoprostol tablets. Bleeding can occur for 10 to 16 days and it is usual for bleeding to be heavier than a normal period for 2 to 3 days. Contact your doctor immediately if you find you have very heavy bleeding and have soaked more than 2 pads per hour over 2 hours.

Infection

Serious infections are very rare in a medical termination of pregnancy and can be potentially life threatening. If you have symptoms more than 24 hours after taking misoprostol or 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 the mifepristone tablet

Follow up with your doctor

It is very important for you to receive follow-up with a doctor in the 14-21 days after taking the Mifepristone Linepharma tablet, even if you feel well.

Storage

Mifepristone will be stored within the **MS-2 Step** pack by your doctor or pharmacist under the recommended conditions. It should be kept in a cool, dry place where the temperature stays below 25 degrees C. Store mifepristone in the original packaging.

Keep **MS-2 Step** where children cannot reach it.

MS-2 Step should not be used after the expiry date printed on the **MS-2 Step** pack. If this medicine is used after the expiry date it may not work as well.

Disposal

Any **MS-2 Step** which is not used must 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 and misoprostol may still be present after taking **MS-2 Step**, it is recommended that you avoid getting pregnant again before your next menstrual period.

Product description

What it looks like

The mifepristone 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 is in a blister pack of one tablet. There is one Mifepristone Linepharma pack in each **MS-2 Step** pack.

Ingredients

The mifepristone tablet 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

MS-2 Step is supplied in Australia by:

MS Health

Suite 129, 135 Cardigan Street
Carlton VIC 3053
Australia

**MS Health Nurse After-care
Telephone Service:
1300 515 883 (24 hours)**

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