

MS-2 Step GyMiso® Tablet Pack

Each tablet contains misoprostol 200 micrograms

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 and GyMiso® misoprostol 200 microgram tablets (this medicine in the purple box).

Mifepristone Linepharma = mifepristone

GyMiso® = misoprostol

GyMiso® misoprostol 200 microgram tablets must be taken only after having taken the mifepristone tablet.

What is in this leaflet

This leaflet answers some common questions about misoprostol tablets 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 misoprostol tablets 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 misoprostol is used for

GyMiso® contains misoprostol. It belongs to a group of medicines called prostaglandins. It acts like prostaglandin E₁. Misoprostol induces contractions of the smooth muscle and relaxation of the cervix. These properties help open the cervix and push out the contents of the uterus.

Misoprostol can therefore be used to terminate a pregnancy.

Misoprostol is given in combination with another medicine called Mifepristone Linepharma (in the green box), which blocks progesterone, a hormone that is needed for pregnancy to continue. Both medicines are contained within the MS-2 Step pack, and they are recommended for termination of pregnancy up to 63 days after the first day of 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 misoprostol

When you must not be given it

You should not be given misoprostol 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 misoprostol, or any other prostaglandins or any of the other ingredients listed at the end of this leaflet
- you cannot take mifepristone or have any allergies to mifepristone
- you have not taken, first, the mifepristone tablet
- 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 should not use this medicine after the expiry date printed on the GyMiso® 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 misoprostol if advised to do so by your doctor.

There is limited information on the use of misoprostol in adolescents less than 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 misoprostol

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:

- heart or cardiovascular disease
- epilepsy
- asthma
- porphyria
- kidney problems
- liver problems
- malnutrition
- problems with your adrenal glands
- 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), 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 and misoprostol tablets contained within 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 misoprostol may interfere with each other.

Different medicines may be affected by misoprostol, 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 misoprostol.

How misoprostol is given

How much to take

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

Misoprostol is usually taken 36 to 48 hours after you have taken the mifepristone tablet. You will need to take the **four** misoprostol tablets (misoprostol 800 micrograms) which are in the purple box. These are taken as four tablets in one dose.

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.

How to take misoprostol

Misoprostol should be taken by holding the tablets in your mouth, between the cheek and gum (buccal method), for 30 minutes before swallowing any fragments with water.

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

After you take misoprostol tablets, you should stay at home and rest for 3 hours.

Vaginal bleeding will 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.

If bleeding does not occur, it is very important that you contact your doctor immediately. For some patients, the doctor may prescribe a repeat dose of misoprostol or a termination can be arranged using another method.

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 immediately in order to schedule an appointment.

In rare cases, a termination can occur after you take the mifepristone tablet 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 misoprostol tablets and it has been more than 48 hours after you have taken a mifepristone tablet.

If you are given too much (overdose)

Misoprostol 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 doctor's 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, that 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

Misoprostol should not be taken if you are breastfeeding.

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 these medicines.

If you plan to become pregnant, tell your doctor that you have been given this medicine.

Your doctor can discuss with you the risks and benefits involved.

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 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 occurring 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 misoprostol

Storage

Misoprostol should be stored within the MS-2 Step pack and be kept in a cool, dry place where the temperature stays below 25 degrees C. Store misoprostol 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 misoprostol and mifepristone 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

Misoprostol is presented in a box containing a blister pack of 4 white, round, flat tablets with ML on one side and 200 on the other. Each tablet contains 200 micrograms of misoprostol. There is one GyMiso® pack in each MS-2 Step pack.

Ingredients

Each misoprostol tablet contains the active ingredient misoprostol plus hypromellose, microcrystalline cellulose, sodium starch glycolate, and hydrogenated castor oil.

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

Supplier

MS-2 Step is supplied in Australia by:

MS Health Pty Ltd

Suite 60, 278 Church Street,
Richmond, VIC, Australia, 3121.

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

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