

MS-2 Step[®] Mifepristone Linepharma

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 healthcare practitioner (doctor, nurse 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 MS -2 Step Mifepristone Linepharma?

MS-2 Step[®] is a composite pack product containing Mifepristone Linepharma 200 mg tablet and GyMiso[®] misoprostol 200 microgram tablets. MS -2 Step Mifepristone Linepharma contains the active ingredient mifepristone. MS -2 Step Mifepristone Linepharma is used to terminate a pregnancy up to 63 days after your last menstrual period when given in combination with MS - 2 Step GyMiso[®].

For more information, see Section [1. Why am I using MS -2 Step Mifepristone Linepharma?](#) in the full CMI.

2. What should I know before I use MS -2 Step Mifepristone Linepharma?

Do not use 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 healthcare practitioner 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 MS -2 Step Mifepristone Linepharma?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with MS -2 Step 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 MS -2 Step Mifepristone Linepharma?

MS -2 Step Mifepristone Linepharma tablet should be taken first and then, 36 to 48 hours later, take the MS - 2 Step GyMiso[®] tablets. The MS -2 Step Mifepristone Linepharma tablet should be swallowed with water. It is recommended that the MS -2 Step Mifepristone Linepharma tablet should be taken on an empty stomach 2 hours before or 2 hours after a meal.

More instructions can be found in Section [4. How do I use MS -2 Step Mifepristone Linepharma?](#) in the full CMI.

5. What should I know while using MS -2 Step Mifepristone Linepharma?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, nurse, dentist or pharmacist you visit that you are using MS -2 Step Mifepristone Linepharma.• Contact your healthcare practitioner immediately if you forget to take the dose of MS - 2 Step GyMiso[®] tablets in the purple box, and it is greater than 48 hours after you have taken MS -2 Step Mifepristone Linepharma tablet.• It is important to have a follow up with your doctor 14-21 days after you take MS -2 Step Mifepristone Linepharma
Things you should not do	<ul style="list-style-type: none">• Do not take grapefruit juice when you are treated with MS – 2 Step 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 MS - 2 Step Mifepristone Linepharma affects you.
Drinking alcohol	Tell your healthcare practitioner (doctor, nurse or pharmacist) if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none">• MS - 2 Step Mifepristone Linepharma should be stored within the MS - 2 Step composite pack and be kept in a cool and dry place where the temperature stays below 25 degrees C• Keep MS -2 Step where children cannot reach it

For more information, see Section [5. What should I know while using MS – 2 Step Mifepristone Linepharma?](#) in the full CMI.

6. Are there any side effects?

The common side effects include headache, spotting, cramps, breast tenderness, fainting. Serious side effects include serious skin reactions, prolonged heavy vaginal bleeding, infections that can be potentially life threatening, 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: It is very important that all patients receiving this medication are followed up by a healthcare 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 MS -2 Step Mifepristone Linepharma.

MS – 2 Step[®] Mifepristone Linepharma

Active ingredient: *mifepristone*

Consumer Medicine Information (CMI)

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

This leaflet provides important information about using MS -2 Step Mifepristone Linepharma contained within the MS-2 Step pack. **You should also speak to your doctor, nurse or pharmacist if you would like further information or if you have any concerns or questions about using MS -2 Step Mifepristone Linepharma.**

Where to find information in this leaflet:

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

1. Why am I using MS -2 Step Mifepristone Linepharma?

MS -2 Step 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.

MS -2 Step Mifepristone Linepharma 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 healthcare practitioner (doctor, nurse or pharmacist) if you have any questions about why MS-2 Step has been prescribed for you.

2. What should I know before I use MS -2 Step Mifepristone Linepharma?

Warnings

Do not use MS -2 Step 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 to emergency medical care in the next 14 days
- your doctor suspects an ectopic pregnancy (the egg is implanted outside the womb)
- if you have an intra-uterine device (IUD), as this needs to be removed.
- your pregnancy has not been confirmed by an ultrasound scan or biological test such as urine or serum HCG
- 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 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.

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.

Check with your healthcare practitioner 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
 - asthma
 - epilepsy
 - porphyria
 - are taking anticoagulants
 - are taking long term corticosteroids including inhaled corticosteroids for the treatment of asthma

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.

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 healthcare practitioner if you are pregnant or intend to become pregnant.

Do not use MS -2 Step Mifepristone Linepharma if:

- your healthcare practitioner suspects an ectopic pregnancy (the egg is implanted outside the womb)
- 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

Talk to your healthcare practitioner if you are breastfeeding or intend to breastfeed. MS -2 Step Mifepristone Linepharma should not be taken if you are breast-feeding.

3. What if I am taking other medicines?

Tell your healthcare practitioner if you are taking any other medicines, including any medicines, vitamins or

supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with MS -2 Step 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 MS -2 Step 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.

Grapefruit juice should not be taken when you are treated with MS -2 Step Mifepristone Linepharma.

4. How do I use MS – 2 Step Mifepristone Linepharma?

How much to take

- Your healthcare practitioner will tell you how many tablets you need to take and when to take them.
- The usual dose of MS – 2 Step Mifepristone Linepharma is 200 mg (one tablet) in the green box.

When to take

- It is necessary to take the MS -2 Step Mifepristone Linepharma tablet first and then, 36 to 48 hours later, take the MS -2 Step GyMiso® tablets. This must be done in this order for the medicines to work.
- It is recommended that the MS -2 Step Mifepristone Linepharma tablet should be taken on an empty stomach - 2 hours before or 2 hours after a meal.

How to take

- The MS -2 Step Mifepristone Linepharma 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 your healthcare practitioner.

If you forget to take your dose of MS - 2 Step GyMiso®

Contact your healthcare practitioner immediately if you forget to take the dose of MS - 2 Step GyMiso® tablets in the purple box, and it is greater than 48 hours after you have taken MS - 2 Step Mifepristone Linepharma tablet.

If you use too much MS – 2 Step Mifepristone Linepharma

MS – 2 Step Mifepristone Linepharma is available as a single tablet pack, and it is prescribed for you by your healthcare practitioner. An overdose is not likely to occur. Ask your doctor or healthcare practitioner if you have any concerns. If you think that you have used too much MS – 2 Step Mifepristone Linepharma, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using MS – 2 Step Mifepristone Linepharma?

Things you must do

- After you take MS - 2 Step GyMiso® 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 MS - 2 Step GyMiso® or during the next few days. The bleeding lasts on average for 10 to 16 days and may be heavy. 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 MS - 2 Step Mifepristone Linepharma can cause harm to your baby. It is believed, though, MS - 2 Step GyMiso® 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.

It is very important that you have follow up with your doctor or healthcare practitioner 14 to 21 days after you take MS - 2 Step 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 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.

Tell your doctor if you are a smoker.

Call your healthcare practitioner straight away:

- In case of heavy and prolonged bleeding, you should contact your healthcare practitioner or clinic immediately to get advice and care. In a few cases, a termination can occur after you take MS - 2 Step Mifepristone Linepharma but before you take MS - 2 Step GyMiso®. 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.

Remind any doctor, nurse, dentist or pharmacist you visit that you are using MS-2 Step 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 MS - 2 Step Mifepristone Linepharma affects you.

Drinking alcohol

Tell your healthcare practitioner if you drink alcohol.

Looking after your medicine

- MS - 2 Step Mifepristone Linepharma should be stored within the MS-2 Step pack
- Store below 25 degrees 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

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

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 healthcare practitioner if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Gastrointestinal upset</p> <ul style="list-style-type: none"> Nausea Vomiting Diarrhoea <p>Tiredness related</p> <ul style="list-style-type: none"> Fainting Dizziness Fatigue Headache <p>Vagina related</p> <ul style="list-style-type: none"> Vaginal bleeding which may be heavy or prolonged Spotting <p>Pain related</p> <ul style="list-style-type: none"> Abdominal discomfort Abdominal pain Cramps Breast tenderness <p>Skin related</p> <ul style="list-style-type: none"> Hot flushes Skin rashes or itching <p>Infection related</p> <ul style="list-style-type: none"> Chills and /or fever 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

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 	<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>

may appear at the initiation of treatment.

Bleeding related

- Vaginal bleeding usually starts a few hours after taking MS – 2 Step GyMiso® 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 related

- 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 MS – 2 Step GyMiso® or ongoing abdominal pain, or feeling unwell or feeling weak, with or without a fever, you should contact your doctor without delay.

Tell your healthcare practitioner 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 healthcare practitioner before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a prescription.

What MS – 2 Step 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 MS - 2 Step Mifepristone Linepharma looks like

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

Australian registration number: AUST R 210574

Who distributes MS - 2 Step Mifepristone Linepharma

MS-2 Step is supplied in Australia by:

MS Health Pty Ltd

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

Ph: 1300 515 883

MS-2 Step® is a registered trademark of MSI

Reproductive Choices (UK).

Mifepristone Linepharma and GyMiso® are licensed from Linepharma International Limited (UK).

This leaflet was prepared in June 2023.

MS-2 Step[®] GyMiso[®]

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 healthcare practitioner (doctor, nurse 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 MS-2 Step GyMiso[®]?

MS-2 Step GyMiso[®] contains the active ingredient misoprostol. MS-2 Step GyMiso[®] is used to terminate pregnancy when given in combination with another medicine called Mifepristone Linepharma.

For more information, see Section [1. Why am I using MS-2 Step GyMiso[®]?](#) in the full CMI.

2. What should I know before I use MS-2 Step GyMiso[®]?

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

Talk to your healthcare practitioner 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 MS-2 Step GyMiso[®]?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with MS-2 Step GyMiso[®] 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 MS-2 Step GyMiso[®]?

- MS-2 Step GyMiso[®] is usually taken 36-48 hours after you have taken MS – 2 Step Mifepristone Linepharma tablet. You will need to take the four MS-2 Step GyMiso[®] tablets in one dose.
- MS-2 Step GyMiso[®] 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 MS-2 Step GyMiso[®] should be taken on an empty stomach before or after a meal.

More instructions can be found in Section [4. How do I use MS-2 Step GyMiso[®]?](#) in the full CMI.

5. What should I know while using MS-2 Step GyMiso[®]?

Things you should do	<ul style="list-style-type: none">Remind any doctor, nurse, dentist or pharmacist you visit that you are using MS-2 Step GyMiso[®]MS-2 Step GyMiso[®] tablets must be taken only after taking the MS – 2 Step Mifepristone Linepharma tablet provided in the MS-2 Step pack.It is important to keep all healthcare practitioner appointments so that your progress can be checked
Things you should not do	<ul style="list-style-type: none">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	<ul style="list-style-type: none">Be careful before you drive or use any machines or tools until you know how MS-2 Step GyMiso[®] affects you.
Drinking alcohol	<ul style="list-style-type: none">Tell your healthcare practitioner if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none">MS-2 Step GyMiso[®] should be stored within the MS-2 Step composite pack and be kept in a cool and dry place where the temperature stays below 25 degrees CKeep MS -2 Step where children cannot reach it

For more information, see Section [5. What should I know while using while using MS-2 Step GyMiso[®]?](#) in the full CMI.

6. Are there any side effects?

The common side effects include headache, spotting, cramps, breast tenderness, fainting, abdominal discomfort, vomiting, diarrhea, fever. Serious side effects include prolonged heavy vaginal bleeding, infections that can be potentially life threatening, ongoing abdominal pain, or feeling unwell or feeling weak, with or without a fever.

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: It is very important that all patients receiving this medication are followed up by a healthcare 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[®] GyMiso[®]

Active ingredient: *misoprostol*

Consumer Medicine Information (CMI)

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.

This leaflet provides important information about using MS-2 Step GyMiso[®]. **You should also speak to your doctor, nurse or pharmacist if you would like further information or if you have any concerns or questions about using MS-2 Step GyMiso[®].**

Where to find information in this leaflet:

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

1. Why am I using MS-2 Step GyMiso[®]

MS-2 Step GyMiso[®] contains the active ingredient misoprostol. MS-2 Step GyMiso[®] belongs to a group of medicines called prostaglandins. It acts like prostaglandin E₁. MS-2 Step GyMiso[®] 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.

MS-2 Step GyMiso[®] can therefore be used to terminate a pregnancy. It 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 healthcare practitioner if you have any questions about why MS-2 Step has been prescribed for you.

2. What should I know before I use MS-2 Step[®] GyMiso[®]

Warnings

Do not use MS-2 Step GyMiso[®] if:

- you are allergic to misoprostol, mifepristone (or any prostaglandin) or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- 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 an ultrasound scan or biological test such as urine or serum HCG
- 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 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

If you are under 18 years of age, you should only take MS-2 Step GyMiso[®] if advised to do so by your doctor.

There is limited information on the use of MS-2 Step GyMiso[®] in adolescents less than 18 years of age.

Check with your healthcare practitioner if you:

- have any other 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
- take any medicines for any other condition

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

Your healthcare practitioner 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 hours assistance.

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 healthcare practitioner if you are pregnant or intend to become pregnant.

You should not be given MS-2 Step GyMiso® if:

- your healthcare practitioner suspects an ectopic pregnancy (the egg is implanted outside the womb)
- 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 healthcare practitioner if you are breastfeeding or intend to breastfeed.

MS-2 Step GyMiso® should not be taken if you are breastfeeding.

3. What if I am taking other medicines?

Tell your healthcare practitioner if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with MS-2 Step GyMiso® and affect how it works.

Different medicines may be affected by MS-2 Step GyMiso® 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 healthcare practitioner may have more information on medicines to be careful with or avoid while being treated with MS-2 Step GyMiso®.

Check with your healthcare practitioner if you are not sure about what medicines, vitamins or supplements you are taking and if these affect MS-2 Step GyMiso®.

4. How do I use MS-2 Step GyMiso®?

How much to take

- Your healthcare practitioner will tell you how many tablets you need to take and when to take them. MS-2 Step GyMiso® is usually taken 36 to 48 hours after you have taken the MS-2 Step Mifepristone Linepharma tablet. You will need to take the four MS-2 Step GyMiso® tablets (misoprostol 800 micrograms) which are in the purple box. These are taken as four tablets in one dose.

When to take

- It is necessary to take the MS-2 Step Mifepristone Linepharma tablet first and then, 36 to 48 hours later, take the MS-2 Step GyMiso® tablets. This must be done in this order for the medicines to work.
- It is recommended that MS-2 Step GyMiso® should be taken on an empty stomach 2 hours before or after a meal.

How to take

- MS-2 Step GyMiso® 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.

If you forget to use MS-2 Step GyMiso®

Contact your healthcare practitioner immediately if you forget to take MS-2 Step GyMiso® tablets and it has been more than 48 hours after you have taken a MS-2 Step Mifepristone Linepharma tablet.

If you use too much MS-2 Step GyMiso®

MS-2 Step GyMiso® is prescribed for you by your healthcare practitioner. An overdose is not likely to occur. Ask your healthcare practitioner if you have any concerns. If you think that you have used too much MS-2 Step GyMiso®, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using MS-2 Step GyMiso®?

Things you should do

- After you taken MS-2 Step GyMiso® 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 MS-2 Step GyMiso® 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 healthcare practitioner 14 to 21 days after you take MS – 2 Step Mifepristone Linepharma, to ensure that the termination was complete, because incomplete termination will increase the risk of serious infection or bleeding.**
- 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 MS-2 Step GyMiso® 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.
- 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.

Call your healthcare practitioner straight away:

- If bleeding does not occur, it is very important that you contact your doctor immediately. For some patients, the healthcare practitioner may prescribe a repeat dose of MS-2 Step GyMiso® or a termination can be arranged using another method.
- 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 MS -2 Step Mifepristone Linepharma tablet but before you take MS-2 Step GyMiso®. 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.

Remind any doctor, nurse, dentist or pharmacist you visit that you are using MS–2 Step GyMiso®.

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 MS-2 Step GyMiso® affects you.

Drinking alcohol

Tell your healthcare practitioner if you drink alcohol.

Looking after your medicine

- MS-2 Step GyMiso® should be stored within the MS-2 Step pack
- Store below 25 degrees 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

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

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 healthcare practitioner if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Gastrointestinal upset <ul style="list-style-type: none">• Nausea• Vomiting• Diarrhoea Tiredness related <ul style="list-style-type: none">• Fainting• Dizziness• Fatigue• Headache Vagina related <ul style="list-style-type: none">• Vaginal bleeding• Spotting	Speak to your doctor if you have any of these less serious side effects and they worry you.

Pain related <ul style="list-style-type: none"> Abdominal discomfort Abdominal pain Cramps Breast tenderness Skin related <ul style="list-style-type: none"> Hot flushes Skin rashes or itching Infection related <ul style="list-style-type: none"> Chills and /or fever 	
---	--

Serious side effects

Serious side effects	What to do
Bleeding related <ul style="list-style-type: none"> 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 related <ul style="list-style-type: none"> 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. 	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.

Tell your healthcare practitioner 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 healthcare practitioner before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a prescription.

What MS-2 Step GyMiso® contains

Active ingredient (main ingredient)	misoprostol
Other ingredients (inactive ingredients)	Hydrogenated castor oil Hypermellose Microcrystalline cellulose Sodium starch glycolate type A
Potential allergens	No

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

What MS-2 Step GyMiso® looks like

MS-2 Step GyMiso® 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.

Australian registration number: AUST R 210574.

Who distributes MS-2 Step GyMiso®

MS-2 Step is supplied in Australia by:

MS Health Pty Ltd

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

Ph: 1300 515 883

GyMiso® is licensed from Linepharma International Ltd, UK

MS-2 Step® is a registered trademark of MSI Reproductive Choices (UK). Mifepristone Linepharma and GyMiso® are licensed from Linepharma International Limited (UK).

This leaflet was updated in June 2023.