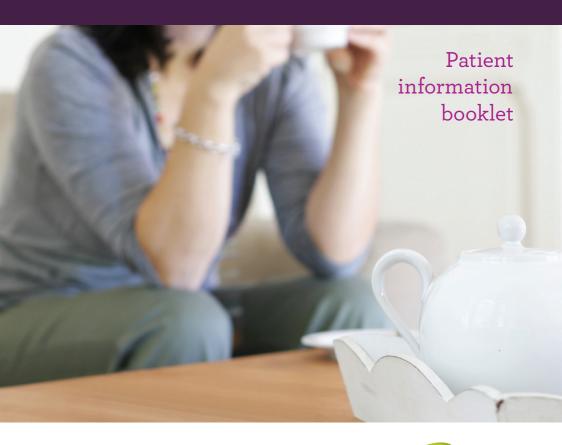
A CHOICE IN THE COMFORT OF YOUR OWN HOME SUPPORTED BY YOUR HEALTHCARE PRACTITIONER.

MS-2 Step® (mifepristone, misoprostol) for early termination of pregnancy up to 63 days gestation







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Please call your healthcare practitioner if you experience problems or are at all concerned about side effects. Your healthcare practitioner may provide you with information about other health services you can contact if you have questions or concerns.



Please read this information carefully. We encourage you to ask questions about the information provided. You may also wish to discuss the information in this patient information booklet with a friend or family member.

We request that you keep this information booklet in the event that it is needed for future reference. Before commencing the MS-2 Step® process you must read the Consumer Medicine Information contained in both the Mifepristone Linepharma® box and GyMiso® box. If you have further questions please speak with your healthcare professional.

This patient information booklet contains information regarding medical termination of pregnancy.

WARNING: It is very important that all patients receiving this medication obtain follow-up from 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.

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The medicines used for a termination of first trimester pregnancy – mifepristone and misoprostol

Each pack of MS-2 Step® (mifepristone, misoprostol) contains 1 pack of Mifepristone Linepharma® (mifepristone) and 1 pack of GyMiso® (misoprostol).

Two medicines are used for a medical termination of first trimester pregnancy: first a mifepristone tablet is taken and then 36 to 48 hours later, misoprostol tablets are taken.

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

Misoprostol is a prostaglandin and causes contractions of the uterus and relaxation of the cervix which helps push out the contents of the uterus

Both mifepristone and misoprostol work together to end a pregnancy.

This leaflet provides information about the use of mifepristone and misoprostol for the termination of a first trimester pregnancy. Your healthcare practitioner may have prescribed these medicines for another reason and you should ask them if you have any questions about why these medicines have been prescribed for you.

Before you are given the medicines, you will talk with your healthcare practitioner who may conduct or refer you for an ultrasound. If your pregnancy is no more than 63 days duration and if a medical termination is suitable for you, then you may be eligible to start the treatment.

Before you take the medicines

A medical termination of pregnancy may not be suitable for you, so you should tell your healthcare practitioner if any of the following apply:

- if you are pregnant and wish to continue with your pregnancy
- your pregnancy is assessed as being more than 63 days duration
- you are unable to access emergency medical care in the
 14 days following the start of treatment with mifepristone
- you have a known or suspected ectopic pregnancy (a pregnancy growing outside the uterus)
- you have known or suspected hypocoagulation disease (a bleeding disorder)
- you are taking anticoagulants (drugs that prevent or treat blood clots)
- you suffer from severe disease where it is necessary to take steroids (e.g. asthma uncontrolled by treatment)
- you are taking corticosteroids (medicines such as prednisolone and cortisone, which reduce the activity of your immune system)
- you have adrenal failure
- you have an allergy to either mifepristone and/or misoprostol or prostaglandins
- you have an IUD in place this must be removed before the termination of pregnancy process is started
- you have a pelvic infection.

Mifepristone Linepharma® and GyMiso® are not recommended to be taken if you are breastfeeding.



Please read information carefully

How to take the medicines

There are two steps in the process.

The first step

You will take one tablet of mifepristone.

Some women can experience bleeding between the first and second steps of treatment. Please call your healthcare practitioner or other health service if you are at all worried.

The second step

36 to 48 hours after you take mifepristone you need to take the misoprostol tablets. It is up to you when you take the tablets within this time period. You should plan the process to fit in with your daily schedule.

You will take four misoprostol tablets.

Misoprostol tablets should be taken by holding the tablets in your mouth, between the cheek and gum, for 30 minutes. Any fragments left after 30 minutes can be swallowed with a glass of water.



After this you can expect some vaginal bleeding, cramps and to pass some pregnancy tissue. This commonly occurs within four hours but in some cases may occur anywhere between 30 minutes and 48 hours after taking the misoprostol tablets. The bleeding lasts on average for 10 to 16 days and may be heavy.

Most women require no further medication, however, if no bleeding has occurred within 24 hours after taking the misoprostol, you should contact your healthcare practitioner as soon as possible.

Signs and symptoms of the termination

Below is a list of the most common symptoms you may experience as part of the termination process. It is important to understand these symptoms and any risks that may arise from using this treatment.

Vaginal bleeding

- The onset of bleeding is usually within 4 hours of taking the misoprostol tablets and most women will experience the onset within 48 hours.
- Bleeding can range from light to heavy. Bleeding is usually more than a typical menstrual period.
- Bleeding should diminish once the pregnancy is expelled.
- Vaginal bleeding does not mean that the pregnancy has been expelled. A follow-up assessment is very important, to confirm termination of pregnancy.
- Sometimes bleeding can occur after taking the mifepristone but before taking the misoprostol.
- The bleeding lasts on average for 10 to 16 days. Light bleeding can continue for 30 days or more but does not normally go beyond the first period following your treatment.

Problem bleeding

- If you saturate two (or more) sanitary pads per hour for two consecutive hours this could be "problem bleeding".
- If you experience problem bleeding or are at all concerned about the amount of bleeding you are experiencing, then you should contact your healthcare practitioner or other health service, or attend the emergency department of your local hospital.

Cramping

- Cramping can start within 4 hours of taking the misoprostol tablets.
- Cramping can range from mild to severe and is usually more than a typical menstrual period.
- Significant cramping should diminish once the pregnancy is expelled and does not usually last longer than 24 hours.

Pain management

To help manage your pain, ensure that you:

- rest
- use hot packs on your abdomen or back
- massage the lower abdomen frequently
- take pain relief medications, always as directed by your healthcare practitioner.

Other possible side effects:

- headache
- breast tenderness
- fainting
- hot flushes, skin rashes or itching.



These side effects are usually short term and do not last more than 24 hours.

If you experience problems or are at all concerned about side effects you should contact your healthcare practitioner or other health service.

Possible adverse effects of treatment

Although cramping and bleeding are expected as part of ending a pregnancy, rarely, serious and potentially lifethreatening bleeding, infections or other problems can occur following a medical abortion. The use of this treatment is not risk free.

Prompt medical attention is needed in the following circumstances. You should contact your healthcare practitioner for immediate medical attention if you experience:

- heavy vaginal bleeding (soaking two (or more) sanitary pads per hour for two consecutive hours or have large fist-sized clots)
- prolonged heavy bleeding or severe cramping: it is expected that, on average, bleeding will occur for 10 to 16 days after Mifepristone Linepharma® administration and may initially be heavy - you should return to your healthcare practitioner for any bleeding that occurs after this time
- · cramping which is not improved by pain relief medication
- · fever, chills or malaise lasting six hours or more
- any abnormal vaginal discharge
- severe abdominal pain
- feeling sick (including weakness, nausea, vomiting, diarrhoea, abdominal discomfort, cramps, fatigue, chills) with or without a fever more than 24 hours after taking misoprostol tablets
- severe skin reactions such as widespread rash, redness,
 blistering or peeling skin; or ulcers of the mouth, vagina or eyes
- swelling of the face, lips, tongue and/or larynx or a severe allergic reaction

You should also contact your healthcare practitioner if you are worried about any of the following:

- headache
- breast tenderness
- fainting
- · hot flushes; skin rashes or itching.

It is possible that other side effects may occur in some people which have not been discovered yet. Other side effects not listed in this leaflet may also occur in some people. You should discuss possible side effects that you may experience with your healthcare practitioner.



If you experience problems or are at all concerned about side effects you should contact your healthcare practitioner or other health service, as advised.

If you have questions or concerns call:
If you need to attend your local emergency department, it is located at:
Hospital name:
Hospital address:
Section 6 Follow-up
You MUST adhere to any follow up arrangements or appointments as advised by your healthcare practitioner. Follow up is very important so that they can confirm that the termination of pregnancy is complete and exclude possible complications.
If the termination is not complete, your healthcare practitioner will discuss your treatment options, which may include surgery.
It is recommended that you do not travel away from home during the time that you are bleeding so that you can visit your healthcare practitioner or clinic if necessary.
Your follow up appointment is booked for
Dato:

MSHealth

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