

Patient Information Sheet and Consent Form

Mifepristone and Misoprostol for termination of first trimester pregnancy MS Health – MS-2 Step® (mifepristone, misoprostol)

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 Sheet with a friend or family member.

We request that you keep this information sheet in the event that it is needed for future reference. Further information is available from the Consumer Medicine Information for MS-2 Step® (mifepristone, misoprostol) and from your doctor, nurse or pharmacist.

This Patient Information Sheet contains information regarding medical termination of pregnancy.

What is in this leaflet?

This leaflet provides information about:

1. The medicines used for a termination of pregnancy up to 63 days gestation
2. Before you take the medicines
3. How to take the medicines
4. Signs and symptoms of the termination
5. Possible side effects of treatment
6. Follow-up
7. Consent to treatment.

Section One: 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 doctor may have prescribed these medicines for another reason and you should ask your doctor if you have any questions about why these medicines have been prescribed for you.

Before you are given the medicines, you will talk with the doctor who will perform a physical examination and may conduct an ultrasound. If the doctor assesses that your pregnancy is up to 63 days duration and if a medical termination is suitable for you, then you may be eligible start the treatment.

Section Two: Before you take the medicines

A medical termination of pregnancy may not be suitable for you, so you should tell your doctor 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 within 14 days following the administration of 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.

If your blood group is Rhesus negative, the use of Mifepristone Linepharma® and GyMiso® requires that your doctor will take measures to prevent Rhesus factor sensitisation. Please ask your doctor if you are not sure about your blood group.

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

Section Three: 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 doctor** or the **MS Health 24-hour Nurse After-care Telephone Service on 1300 515 883** 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 doctor as soon as possible.**

Please call **your doctor** or the **MS Health 24-hour Nurse After-care Telephone Service on 1300 515 883** if you are at all worried.

Section Four: 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 doctor or call the **MS Health 24-hour Nurse After-care Telephone Service on 1300 515 883**.

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 doctor.

Other possible side effects:

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

GyMiso® tablets can cause:

- nausea
- vomiting
- diarrhoea
- dizziness
- abdominal discomfort, abdominal pain, cramps
- short term fever and chills

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 doctor or the **MS Health 24-hour Nurse After-care Telephone Service on 1300 515 883**.

Section Five: Possible adverse effects of treatment

Although cramping and bleeding are expected as part of ending a pregnancy, rarely, serious and potentially life-threatening 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 doctor 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 the clinic for any bleeding 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.

You should also contact your doctor 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 doctor.

If you experience problems or are at all concerned about side effects you should contact your doctor or the **MS Health 24-hour Nurse After-care Telephone Service on 1300 515 883**. You should contact your doctor or the MS Health After-care number, even if you are concerned about symptoms that are not listed here.

If you are directed to attend your local emergency department it is located at:

Hospital name: _____

Hospital address: _____

Section Six: Follow up

You **MUST** adhere to any follow up arrangements or appointments as advised by your doctor. Follow up is very important so that your doctor can confirm that the termination of pregnancy is complete and exclude possible complications.

If the termination is not complete, your doctor 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 doctor or clinic if necessary.

Your follow up appointment is booked for

Date:		Time:	
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Section Seven: Consent to treatment

Please note that the risks mentioned in the list below and in the patient information sheet are not exhaustive or inclusive of all possible complications, but are rather the ones generally known or associated with a medical termination of pregnancy. Some of the possible side effects are mentioned in Section Four and Five of this leaflet.

In addition, please note:

- there is approximately a 2-7% chance that the course of treatment will not be fully effective, in which case you will need to have a surgical procedure to complete the abortion. If you have a continuing pregnancy and decide to keep the pregnancy, foetal malformations from the use of misoprostol may occur. The effect of mifepristone on a foetus is not known.
- there is approximately a 1-2% chance that you will require surgery to manage ongoing or heavy bleeding.
- there is approximately a 0.1-0.2% risk of requiring a blood transfusion due to haemorrhage (heavy bleeding).
- serious infections are very rare in a medical termination of pregnancy and can be potentially life threatening. Symptoms of persistent abdominal pain or feeling unwell or feeling weak with or without a fever following the treatment should be reported to your doctor without delay.
- ectopic pregnancy (growing outside the uterus) is a complication of pregnancy not of a medical termination of pregnancy.

I acknowledge that any ultrasound study, if carried out, was only used to confirm and date my pregnancy.

PLEASE READ CAREFULLY BEFORE SIGNING:

I, (print name): _____

of, (print address): _____

consent to Medical Termination of Pregnancy using mifepristone and misoprostol.

The nature, consequences and risks of this treatment have been explained to me, as well as alternatives, including not proceeding with treatment.

I have been informed of the risks and side effects of this treatment and acknowledge the risks outlined above, including treatment failure which would require a surgical procedure to complete the abortion.

I understand that if I decide not to complete the treatment once it has begun, or if treatment fails to end the pregnancy, there is a significant risk of harm to the foetus if I continue the pregnancy.

I am aware that I must comply with any follow up arrangements as advised by my doctor.

I have received written information about the treatment and aftercare which has been discussed and explained to me in my first language, and have had the opportunity to ask questions.

I am satisfied that I have been given the opportunity to explore all options regarding my pregnancy and am consenting to termination of this pregnancy of my own freewill.

Patient name: _____

Signature: _____ **Date:** _____

Guardian name (if required): _____

Signature: _____ **Date:** _____

I confirm that, in my opinion, the patient understands the nature and purposes of the combination of medications used to perform a medical abortion, which has been explained to her in terms suited to her understanding and is able to give informed consent. The patient meets the legal requirements for termination of pregnancy in the state of _____.

Doctor name: _____

Signature: _____ **Date:** _____

Consent for optional follow-up communication

MS Health offers a follow-up communication 3 to 5 days after mifepristone is taken. This message will also include the 24-hour Nurse After-care Telephone Service number so that you can contact us.

I, (print name) _____ hereby consent to receive a follow-up message from MS Health (Maries Stopes International Australia) 3 to 5 days after I take mifepristone.

Mobile number (for SMS Text Message): _____

Signature: _____ **Date:** _____