

PATIENT INFORMATION SHEET

Mifepristone and Misoprostol for termination of first trimester pregnancy

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 both Mifepristone Linepharma and GyMiso (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 contains 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. A consent to treatment form will be provided separately.

Section One: The medicines used for a termination of first trimester pregnancy – mifepristone and 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.

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
- If your pregnancy is assessed as being more than 63 days gestation
- If you have a known or suspected ectopic pregnancy (a pregnancy growing outside the uterus)
- You have a 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 (eg 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 sensitization. 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 24hour 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. You can take four tablets all at once OR you can take two tablets, wait two hours and then take the other two tablets. Your doctor will tell you how to take the tablets.

Misoprostol tablets are by 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 necessary, 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 24hours.

Pain Management:

To help manage you pain, you can:

Rest; take pain relief medications as prescribed; use heat packs on your abdomen or back; massage the lower abdomen frequently

Other Possible Side Effects :

- Headache
- Breast tenderness
- Fainting
- Hot flushes, skin rashes, 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 for 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 bleeding occurring 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, 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.

Section Six: Follow up

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

You will be given a pathology form to have a repeat pregnancy blood test 7 days after you have taken the second dose of medication. The procedure is complete if your pregnancy levels have dropped by 80%.

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.

At Gateway Health, we will make you an appointment for 2 weeks after medical termination to discuss these results.