

Mifegymiso

Mifepristone and Misoprostol

for termination of first
trimester pregnancy



Mifegymiso

Medication Guide



Important: Read First

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 Medication Guide with your caregiver or a friend or family member.

We request that you keep this Medication Guide in the event that it is needed for future reference. Further information is available from your doctor, nurse practitioner, Info-Health or pharmacist.

This Medication Guide contains information regarding medical termination of pregnancy.

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

Each pack of Mifegymiso (mifepristone, misoprostol) contains **1 green pack of mifepristone** and **1 orange pack of misoprostol**.

Two medicines are used for a medical termination of first trimester pregnancy: first a mifepristone tablet is taken and then 24 to 48 hours later, misoprostol tablets are taken. Four (4) misoprostol tablets are taken at the same time.

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 guide provides information about the use of mifepristone and misoprostol for the termination of a first trimester pregnancy.

Before you take 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 49 days duration and if a medical termination is suitable for you, then you may be eligible to start the treatment.

2 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:

- you are pregnant and wish to continue with your pregnancy
- your pregnancy is assessed as being more than 49 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 Mifegymiso requires your doctor to take measures to prevent Rhesus factor sensitization. Please ask your doctor if you are not sure about your blood group.

Mifegymiso is not recommended to be taken if you are breastfeeding.

3 How to take the medicines

There are two steps in the process.

THE FIRST STEP

One (1) tablet of Mifepristone will be taken orally administered under the supervision of your Health Care Provider.

Some women can experience bleeding between the first and second steps of treatment. Please call your doctor, clinic, pharmacist, or the Info-Health telephone line, if you are at all worried.

THE SECOND STEP

24 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 (4) misoprostol tablets at the same time.

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 4 hours but in some cases may occur anywhere between 30 minutes and 48 hours after taking the misoprostol tablets. It is recommended to rest for 3 hours after taking the misoprostol tablets. The bleeding lasts on average for 10 to 16 days and may be heavy.

4 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 terminated.
- vaginal bleeding does not mean that the pregnancy tissues has been expelled but it is normal to see blood clot and tissues. **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 2 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, clinic, pharmacist, or the Info-Health telephone line.

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. This 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

MISOPROSTOL 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, clinic, pharmacist, or the Info-Health telephone line.

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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 Mifegymiso administration and may initially be heavy. You should return to the clinic if any bleeding occurs after this time
- cramping which is not improved by pain relief medication
- fever, chills or malaise lasting 6 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 have a troublesome symptom or side effect that becomes bad enough to interfere with your daily activities, talk to your doctor.

If you have serious symptoms or side effects, get immediate medical help. Contact your doctor, clinic, or go to the nearest medical emergency centre.

IN ADDITION, PLEASE NOTE:

- there is approximately a 2%-4.8% 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 Mifegymiso or mifepristone or misoprostol may occur.
- 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.

6 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.

For general product medication information you can contact **Celopharma** toll free, **1-877-230-4227**.



Important Numbers

YOUR DOCTORS' PHONE NUMBER: _____

ACTION CANADA FOR SEXUAL HEALTH AND RIGHTS

www.sexualhealthandrights.ca

call toll free 1-888-642-2725

NATIONAL ABORTION FEDERATION HOTLINE

www.nafcanada.org

call toll free 1-800-772-9100

Weekdays: 7:00 A.M.–11:00 P.M. Eastern time

Saturdays and Sundays: 9:00 A.M. – 9:00 P.M.

PROVINCIAL /TERRITORIAL TELEHEALTH/TELEMEDICINE LINES TO CONTACT IF YOU HAVE CONCERNS AND/OR QUESTIONS

ALBERTA

ALBERTA TELEHEALTH: www.myhealth.alberta.ca

HEALTH LINK 24/7 DIAL: 8-1-1

BRITISH COLUMBIA

www.healthlinkbc.ca

BC HEALTHGUIDE NURSELINE THROUGHOUT BC: 8-1-1

www.optionsforsexualhealth.org/sex-sense

THROUGHOUT BC: 1-800-SEX SENSE (1-800-739-7367)

LOWER MAINLAND: 604-731-7803

MANITOBA

HEALTHLINKS: www.wrha.mb.ca/healthinfo/healthlinks/

WITHIN WINNIPEG: 204-788-8200

TOLL-FREE THROUGHOUT MANITOBA: 1-888-315-9257

NEW BRUNSWICK

TELECARE: www.gnb.ca/0217/tele-care-e.asp

THROUGHOUT NB: 8-1-1

NORTHWEST TERRITORIES

www.hss.gov.nt.ca

NOVA SCOTIA

HEALTH LINKS: www.nshealthlink811.ca

FOR NON-EMERGENCY HEALTH INFORMATION AND SERVICES: 8-1-1

HEARING IMPAIRED: 7-1-1

ONTARIO

TELEHEALTH ONTARIO:

www.ontario.ca/page/get-medical-advice-telehealth-ontario

1-866-797-0000

TTY: 1-866-797-0007

QUEBEC

INFO-SANTÉ: <http://sante.gouv.qc.ca/systeme-sante-en-bref/info-sante-8-1-1/>

THROUGHOUT QUEBEC: 8-1-1

SASKATCHEWAN

www.saskatchewan.ca/residents/health/accessing-health-care-services/healthline

HEALTHLINE: 8-1-1

TTY: 1-888-425-4444

YUKON

YUKON HEALTH GUIDE: www.ykhealthguide.org

TOLL FREE: 1-800-661-0408, LOCAL 3673

PROVINCIAL/TERRITORIAL TELEHEALTH/TELEMEDICINE LINES

CANADIAN WOMEN'S HEALTH NETWORK

WWW.CWHN.CA/EN/YOURHEALTH/PROVINCIALHEALTHLINES

CELOPHARMA

www.celopharma.com

TOLL FREE: 1-877-230-4227

NOTES:



For additional information call **1-877-230-4227**
or visit us at **www.celopharma.com**