



Guidelines for Pharmacists Dispensing Mifegymiso in Manitoba

{Updated July 2019}

Introduction

In July 2015, Health Canada approved Mifegymiso for medical abortions and established conditions for distribution and administration of the product. Mifegymiso is a combination of two drugs, mifepristone and misoprostol, for the safe medical termination of early pregnancy. The Canadian distributor, Celopharma Inc. launched the product in early 2017.

Health Canada has updated the prescribing information for Mifegymiso since its launch date:

- Since November 7, 2017, the indication is extended to 63 days gestation, the product could be dispensed directly to patients and the Risk Management Plan was changed
- Since April 16, 2019, an ultrasound is no longer required before prescribing Mifegymiso

Background

Mifepristone was first developed in 1981 and the regimen of mifepristone and misoprostol has been used in the United States since 2000 and is now approved in 62 countries {1}. One in three Canadian women will experience an abortion during their lifetime {2} and according to a national study in 2012, less than 4% of abortions were a first term medical abortion {3}.

Mifegymiso is a pre-packed combination product that contains one tablet of mifepristone 200 mg for oral administration, and four tablets of misoprostol 200 mcg for buccal administration. It is packaged in two boxes, one box contains one tablet of mifepristone, and the second box contains four tablets of misoprostol.

Mifepristone 200 mg, when taken initially, blocks progesterone production in the uterus. This is followed one to two days later by four tablets of 200 mcg misoprostol, which will induce contractions and cause a miscarriage. Mifegymiso is approved by Health Canada for the medical termination of a pregnancy with a gestational age up to 63 days. The clinical data to support this indication has demonstrated that 200 mg oral mifepristone followed by buccal administration of 800 mcg misoprostol 24 to 48 hours later effectively induced the termination of pregnancy in 94.2% to 96.4% of women {4}.

Health Canada has approved the Mifegymiso regimen with certain conditions as listed in the product monograph. Health professionals are required to do the following prior to prescribing Mifegymiso:

- Ensure they have adequate knowledge of the use of these medications to prescribe Mifegymiso;
- Discuss informed consent with the patient and provide the patient with the current Patient Medication Information and a completed Patient Information Card;
- Exclude ectopic pregnancy and confirm gestational age by an appropriate method;
- Counsel patients on effects and risks of Mifegymiso, including bleeding, infection and incomplete abortion;
- Ensure that patients have access to emergency medical care in the 14 days following the mifepristone dose;

- Schedule follow-up 7-14 days following mifepristone dose to confirm complete pregnancy termination and to monitor for side effects.

Dispensing of Mifegymiso

Mifegymiso can be dispensed directly to patients by a pharmacist or a prescribing health professional.

Mifegymiso can be provided to the patient using the following options:

1. A patient can take the prescription to a pharmacy of their choice and have the medication dispensed directly to them;
2. A patient can take the prescription to a pharmacy of their choice and have the medication delivered to the prescriber's office.

Pharmacist's Role and Responsibilities in Mifegymiso Treatment

1. Pharmacists should ensure they have the requisite knowledge

Pharmacists dispensing Mifegymiso should ensure they have sufficient background knowledge about the drug and legislation surrounding it. While it is not mandatory for pharmacists to complete specific learning modules prior to dispensing Mifegymiso, pharmacists are encouraged to consult learning resources that will assist them in counselling and answering patients' questions about Mifegymiso.

The following are a few resources that may be helpful to pharmacists

- Medical Abortion Training Program, available through [SOGC {Society of Obstetricians and Gynaecologists of Canada} Online Courses](#)
- An educational program available on the manufacturer, [Celopharma's](#) website
- The [Canadian Pharmaceutical Association](#) has a number of resources on medical abortion
- The Canadian Abortion Providers Support has a [Checklist](#) and [Guide for Pharmacists Dispensing Mifegymiso for registered users](#)

2. Provide patient information and monitoring support

Pharmacists should have knowledge of common side effects and potential complications of Mifegymiso therapy in order to counsel patients and answer their questions. A pharmacist must fulfill the counselling requirement, as with all prescriptions, and not make the assumption that the patient has been provided all the necessary information. The prescribing health professional should provide the patient with their contact information in case the patient needs assistance, as well as the manufacturer's 24 hour support line should the patient be unable to reach the prescriber.

3. Professional obligations when a pharmacist exercises their conscientious objection

The CPhM Code of Ethics states that pharmacists shall hold the health and safety of each patient to be of primary consideration and also respect the rights of patients to receive healthcare {5}. The Conscientious Objection practice direction states that a pharmacist is permitted to object to the provision of a pharmacy product or service in the event that they object due to moral or religious beliefs. However, the pharmacist is still obligated to have a practice/procedure in place to ensure that patients are able to obtain services from another pharmacist or pharmacy in a reasonable timeframe. {6}.

Additional Resources

[Health Canada Mifegymiso Update](#): April 16, 2019

[Health Canada Mifegymiso Update](#): November 7, 2017

[Health Canada Regulatory Decision Summary](#): November 6, 2017

[Health Canada Summary Basis of Decision for Mifegymiso](#): January 7, 2016

[Mifegymiso Canadian Product Monograph](#): Accessed July 16, 2019

[Society of Obstetricians and Gynecologists of Canada \(SOGC\) Medical Abortion Training Program](#)
[Celopharma Inc.](#)

[The Canadian Pharmaceutical Association](#)

References

1. Soon JA, Ragsdale P. Mifegymiso: What Pharmacists need to know. The Tablet Ja/Feb 2017, British Columbia Pharmacy Association
https://www.bcpharmacy.ca/system/files/assets/publication/file/Tablet_Jan-Feb_2017_Issue.pdf
2. Guilbert ER, Hayden AS, Jones HE, O'Connell White k, Lichtenberg ES, Paul M, et al. First-trimester medical abortion practices in Canada. National Survey. Can Fam Physician 2016;62:e201-8.
<http://www.cfp.ca/content/62/4/e201.short>
3. Norman WV, Guilbert ER, Okpaleke C, Hayden AS, Jones HE, Lichtenberg ES, Paul M, et al. Abortion health services in Canada. Results of a 2012 national survey. Can Fam Physician 2016;62:e29-17.
<http://www.cfp.ca/content/62/4/e209.full>
4. Health Canada Regulatory Decision: Mifegymiso. November 7, 2017 <https://hpr-rps.hres.ca/reg-content/regulatory-decision-summary-detail.php?linkID=RDS00294>
5. College of Pharmacists of Manitoba, [Code of Ethics Explanatory Document](#) February 10, 2014
6. College of Pharmacists of Manitoba, [Practice Direction: Conscientious Objection](#) July 27, 2018