



College of Pharmacists of Manitoba

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Guidelines for Pharmacists Dispensing Mifegymiso in Manitoba

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 2 drugs, mifepristone and misoprostol, for the safe medical termination of early pregnancy. The Canadian distributor, Celopharma Inc. launched the product in early 2017. On November 7, 2017, Health Canada updated the indication and the Risk Management Plan for 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 1 tablet of mifepristone, and the second box contains 4 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 ultrasound;
- 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 mifepristone dose;
- Schedule follow-up 7-14 days following mifepristone dose to confirm complete pregnancy termination and to monitor for side effects.



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The following educational and information tools are available:

Patient Medication Information* which provides information for women on the medications to be used, the procedure to be followed before taking the medications, how to take the medications, signs and symptoms of the termination, possible side effects, and follow-up;

A **Patient Consent Form** as a tool for health professionals who may choose to use it to document informed consent;

The **Patient Information Card*** which provides the patient information on: date and time when each medication should be taken; the follow-up appointment date and time; contact information of the health professional or the clinic; and, emergency contact information.

*Each patient should be provided with a printed copy of the MIFEGYMISO Patient Medication Information and the Patient Information Card completed by a health professional.

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. Pharmacist should ensure they have the requisite knowledge

An online training program has been developed jointly by the Canadian Pharmacists Association (CPhA), the Society of Obstetricians and Gynecologists of Canada (SOGC) and the College of Canadian Family Physicians. The program is available as an accredited learning activity through [SOGC eLearning Platform](#).

The program is designed for both physicians and pharmacists and consists of six modules to train health care professionals on the safe use of Mifegymiso.

Pharmacists who will dispense Mifegymiso should complete the SOGC online training program to ensure standards for patient care and counselling are met.

An educational program is also available on the manufacturer, [Celopharma's](#) website.



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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 although the patient has been provided with the Mifegymiso information documents (by the prescribing health professional). 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. A pharmacist is permitted to object to the provision of a certain pharmacy product or service if it appears to conflict with the pharmacist's view of moral or religious beliefs, and if the pharmacist believes that his or her conscience will be harmed by providing the product or service. Notwithstanding, 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 if unable to provide the pharmacy service or unwilling to provide the service due to conscientious objection. (5) The CPhM Community Standards of Practice discusses a Pharmacist's Responsibilities in the Refusal to provide Products or Services for Moral or Religious Reasons. (6)

Additional Resources

[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

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

[Mifegymiso Canadian Product Monograph](#): Accessed November 6, 2017

[Celopharma Inc.](#)

[Canadian Abortion Providers Support](#)



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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, [Community Standards of Practice](#) June 2006