



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.

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 49 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 95.2% to 98.0% of women.(4)

Health Canada has approved the Mifegymiso regimen with certain conditions as listed in the product monograph. Prior to prescribing physicians must:

- Ensure patient access to emergency medical care for 14 days post mifepristone dose
- Schedule follow-up 7-14 days post mifepristone dose to confirm termination
- Exclude ectopic pregnancy and confirm gestational age by ultrasound
- Counsel patients on risks and benefits, including bleeding, infection and incomplete abortion
- Obtain patient's written informed consent to take the drug
- Complete the Mifegymiso Patient Information card and provide a printed copy of the Mifegymiso Patient Medication Guide.

Physicians should complete a training program prior to prescribing Mifegymiso.



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Mifegymiso in Manitoba

In Manitoba, mifegymiso can be provided to the patient using following options:

1. Patient can take the prescription to a pharmacy of their choice and have the drug delivered to the prescriber's office;
2. A physician can provide a prescription to a pharmacy of the patient's choice and have the drug delivered to the prescriber's office.

A pharmacist in Manitoba **cannot** dispense mifegymiso directly to a patient.

In British Columbia and Ontario, the pharmacy regulatory bodies have established guidelines in conjunction with the physician regulatory bodies indicating that patients can have the drug delivered to their physician to dispense to the patient **or** receive the medication directly from the pharmacy. In May, the physician regulatory body in Nova Scotia, also issued a standard supporting the dispensing of Mifegymiso directly to the patient by a pharmacist. The College of Pharmacists in Nova Scotia will soon be publishing guidelines reflecting the same recommendations.

The Canadian distributor, Celopharma Inc. has submitted to Health Canada a request for approval to extend the use of Mifegymiso in a pregnancy with a gestational age up to 63 days and also to allow pharmacists to dispense directly to the patient.

The patient is not required to take either mifepristone or misoprostol in front of their doctor. The product monograph states the mifepristone can be taken as directed by your physician or a member of the medical staff. (5)

Why is the medication recommended to be dispensed by the physician?

A small number of patients who took Mifegymiso presented with more serious complications, such as pelvic infections (endometritis, salpingitis) and vaginal haemorrhages. Rare cases of fatalities were reported, therefore access to emergency care which can provide gynaecological surgical procedures, antibiotic intravenous therapy and blood transfusion in the rare cases where complications occur, is recommended in the labelling to ensure patient's safety. (4) Many other countries which have approved the use of this medication also follow similar conditions whereby the pharmacist is not allowed to dispense directly to the patient. (6, 7)

Pharmacist's role and responsibilities in Mifegymiso treatment

1. Pharmacist must 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



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accredited or non-accredited activity through SOGC eLearning Platform.

<https://sogc.org/online-courses/courses.html>

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. Upon completion of the training program, physicians and pharmacists can join a national online community of health care professionals to access resources and share information. The online initiative, [Canadian Abortion Providers Support](#) (CAPS) program is supported by SOGC, CPhA and the College of Family Physicians of Canada.

2. **Dispense Mifegymiso to the physician using the following options:**

- a. Patient can take the prescription to a pharmacy of their choice and have the drug delivered to the prescriber's office;
- b. A physician can provide a prescription to a pharmacy of the patient's choice and have the drug delivered to the prescriber's office.

The patient will have been given a printed copy of the Mifegymiso Patient Medication Information document and a Patient Information card which is signed by both the patient and the physician. The patient is advised to take their Patient Information card with them if they visit an emergency room or another health care provider.

3. **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 as the patient has been provided with the Mifegymiso information documents. The physician should provide the patient with the physician or clinic 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 physician.

4. **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



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morality or religious beliefs and if the pharmacist believes that his or her conscience will be harmed by providing the product or service. However, the pharmacist is 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. (8) The CPhM Community Standards of Practice discusses a Pharmacist's Responsibilities in the Refusal to provide Products or Services for Moral or Religious Reasons. (9)

Additional Resources

Health Canada Mifegymiso: Myths vs. Facts <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/fact-sheets/mifegymiso-myths-facts.html>

Health Canada Summary Basis of Decision for Mifegymiso: <https://hpr-rps.hres.ca/reg-content/summary-basis-decision-detailTwo.php?linkID=SBD00239>

Mifegymiso Canadian Product Monograph: https://pdf.hres.ca/dpd_pm/00036826.PDF Accessed January 26, 2017

Canadian Pharmacists Association Statement of Health Canada Approval of Mifegymiso: <http://www.pharmacists.ca/advocacy/advocacy-activities/cpha-statement-on-health-canada-approval-of-mifegymiso/>

Celopharma Inc. website <http://www.celopharma.com/>

References

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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. <https://hpr-rps.hres.ca/reg-content/regulatory-decision-summary-detail.php?lang=en&linkID=RDS00032>



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5. Risk Management Communication (Celopharma) – Mifegymiso – Canadian <http://healthy Canadians.gc.ca/recall-alert-rappel-avis/hc-sc/2017/63330a-eng.php>
6. Health Canada – Approved conditions of use for Mifepristone and Misoprostol. Select country comparison. Oct 3, 2016. <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/fact-sheets/approved-conditions-use-mifepristone-misoprostol-sold-canada-mifegymiso.html>
7. Health Canada Mifegymiso: Myths vs. Facts <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/fact-sheets/mifegymiso-myths-facts.html>
8. College of Pharmacists of Manitoba, [Code of Ethics Explanatory Document](#) February 10, 2014
9. College of Pharmacists of Manitoba, [Community Standards of Practice](#) June 2006