

Guidelines for dispensing Mifegymiso®

Background

Mifegymiso®, (mifepristone tablet/misoprostol tablets) is a composite pack containing one mifepristone 200 mg tablet for oral use and four misoprostol 200 mcg tablets for buccal use. Mifegymiso® is indicated for medical termination of a developing intra-uterine pregnancy.

As part of the approval process, Health Canada initially recommended strict conditions of use for this drug, including the requirement that physicians provide the first dose of Mifegymiso® directly to the patient – these conditions were reflected in the product monograph. On May 18, 2017 Celopharma, in collaboration with Health Canada, issued a communication to healthcare professionals to clarify the different requirements and steps to follow in order to prescribe, order, stock, and/or dispense Mifegymiso®.¹ This communication indicates that Module 5 of the Medical Abortion Training Program, available on the Society of Obstetricians and Gynaecologists of Canada (SOGC) online courses website, is available for pharmacists and, while it is not mandatory, pharmacists are encouraged to follow the training program prior to setting up an account with Celopharma and ordering and stocking Mifegymiso®.

On November 7, 2017, upon review of scientific evidence provided by Celopharma, Health Canada authorized several changes regarding the prescribing and dispensing of Mifegymiso®. The changes included allowing the drug to be prescribed for termination of an intra-uterine pregnancy up to 63 days (nine weeks), rather than 49 days (seven weeks) as measured from the first day of the Last Menstrual Period (LMP) in a presumed 28-day cycle, and indicating that Mifegymiso® can be dispensed directly to patients by pharmacists.

On April 16, 2019, Health Canada approved an update to the Mifegymiso® prescribing information. Authorized prescribers may now use their medical judgement to determine if an ultrasound is required before prescribing. Additionally, the product monograph now includes a patient information card, which outlines important information for the patient such as where to go for emergency assistance. All other Mifegymiso® prescribing information remains the same.

There are three ways Mifegymiso® can be provided to patients who are prescribed the drug.

Options include

- patients can take their prescription to a pharmacist of their choice and have the drug delivered by the pharmacy to be administered in the physician's office; or
- patients can take the prescription to a pharmacist of their choice and take the drug at home as directed by the physician, with no requirement to have the ingestion witnessed; or
- if the prescribing physician is authorized to dispense in accordance with the College of Physicians and Surgeons of Alberta (CPSA), the drug can be sold, dispensed and taken by the patient in the physician's office.

Guidance for pharmacists and pharmacy technicians

1. Pharmacists must not prescribe Mifegymiso®.
2. Pharmacists and pharmacy technicians who dispense Mifegymiso® must ensure they have adequate knowledge about the drugs and the legislation and policies for its distribution and administration.
 - a. ACP does not require pharmacy professionals to undertake additional training to dispense Mifegymiso®, however, those who do dispense are strongly encouraged to complete the on line training program provided through the Society of Obstetricians and Gynaecologists of Canada (SOGC Online courses).
3. Prior to dispensing Mifegymiso® a pharmacist must
 - a. ensure the prescriber has clearly indicated the selected option for delivery and administration on the prescription; and
 - b. be satisfied that the patient has had a discussion with the prescriber about how and where they will take Mifegymiso®, and that no confusion exists.
4. Unless the prescription for Mifegymiso® is delivered directly from the pharmacy to the prescriber, a pharmacist must dispense the drug only to the patient and must enter into a dialogue with the patient to
 - a. ensure the patient understands the procedures for the proper use of the drugs,
 - b. provide information about what to expect after taking the drugs and answer any questions the patient may have, and
 - c. meet the additional requirements of the Standards of Practice for Pharmacists and Pharmacy Technicians (SPPPT).

Conscientious objection

Pharmacists and pharmacy technicians are not required to dispense Mifegymiso®. If participating in dispensing a prescription for Mifegymiso® contravenes your moral beliefs, you may exercise conscientious objection, as provided for in ACP's Code of Ethics.

According to Principle 5 of the Code of Ethics, you must assist each patient to obtain appropriate pharmacy services from another pharmacist or health professional within a timeframe fitting the patient's needs if you are unable to provide the pharmacy service, or will not provide the service due to a conscientious objection.

If you intend to exercise your right to conscientious objection you should provide a statement in writing to your supervisor in advance of the possibility of receiving a prescription. You must also familiarize yourself with another pharmacist or pharmacy technician to whom you may guide a patient or physician with a prescription for Mifegymiso®.

References

[Medical Abortion Training Program](#)

[Canadian Abortion Providers Support](#)

[Health Canada Dear Healthcare Professional Letter for MIFEGYMISO - May 8, 2017](#)

[Health Canada Information Update for MIFEGYMISO - November 7, 2017](#)

[Health Canada Information Update for MIFEGYMISO - April 16, 2019](#)

[Alberta Blue Cross Benefact 697](#)

Standards of Practice for Pharmacists and Pharmacy Technicians

ACP Code of Ethics