

DISPENSING MIFEGYMISO®

***Guidance for Pharmacy Professionals Who Are
Dispensing Mifegymiso®***



**Ontario College
of Pharmacists**

Putting patients first since 1871

UPDATED ON: November 13, 2017

Purpose

To provide guidance for pharmacists and pharmacy technicians when dispensing Mifegymiso®.

Introduction

Health Canada originally approved the drug Mifegymiso®, a two-drug combination product that provides a non-surgical option for early abortion in July 2015. Mifegymiso® became available to the Canadian public in January 2017.

Details initially provided by the manufacturer and Health Canada regarding requirements for physician dispensing and patient ingestion of the medication were unclear and there was concern that patient access to therapy could be impaired. Based on these initial requirements, direction from Health Canada indicated that distribution of the medication outside of what is approved in the product monograph would be considered off-label use.

On November 7, 2017, Health Canada released a [Health Product Risk Communication](#) for Mifegymiso® which updates the Product Monograph and Risk Mitigation Plan. These updates extend the gestational age requirement, update the dispensing requirements and remove the requirement for mandatory prescriber education and pharmacist and prescriber registration with the manufacturer.

This guidance has been updated to reflect these changes.

Dispensing Mifegymiso®

There are two possible ways Mifegymiso® can be dispensed according to Health Canada.

1. Patients can take the prescription to a pharmacy of their choice and receive the medication directly from the pharmacist; or
2. Physicians can sell and dispense the medication to the patient in accordance with CPSO's [Dispensing Drugs](#) policy.¹

Administering and Ingesting Mifegymiso®

The updated product monograph for Mifegymiso® requires that the patient take the medication as directed by their health professional. Determining details of medication therapy is a treatment decision between the physician and patient.

¹ As with any medication, patients can also take the prescription to a pharmacy of their choice and have the medication delivered to the physician's office.

Communication between Physicians, Patients and Pharmacists

When dispensing Mifegymiso®, the pharmacist must be aware of and understand the dispensing option the physician and patient have determined would be appropriate. As with any therapy, collaboration and effective communication is necessary for improved patient outcome.

Pharmacist Training

It is the professional responsibility of a pharmacist to ensure that he or she has sufficient knowledge, skills and abilities to competently dispense any medication. A pharmacist must ensure that he or she has undergone the appropriate training and has the required resources to evaluate the potential risks and benefits, and any other relevant factors specific to the situation, to ensure the drug is appropriate for the patient.

There are currently two educational programs available, developed by:

- The [Society of Obstetricians and Gynaecologists of Canada](#) (in collaboration with the College of Family Physicians of Canada (CFPC) and the Canadian Pharmacists Association (CPhA)); and
- [Celopharma Inc.](#)

Responsibilities When Dispensing

Given the serious safety concerns identified with the use of Mifegymiso®, pharmacists are reminded that, as with any medication, they are responsible for providing appropriate follow-up and ensuring that the patient is provided with relevant and sufficient information about the medication, including how to manage risks associated with use. Pharmacists are also required to report any cases of serious or unexpected side effects to Health Canada's MedEffect Canada adverse reaction reporting system.