



Nova Scotia
College of
Pharmacists

PRACTICE GUIDANCE: DISPENSING MIFEGYMISO®

Updated November 16, 2017

Introduction

In June 2015, Health Canada approved the drug product Mifegymiso® for non-surgical abortion in Canada. At that time, Health Canada's approval included a Restricted Distribution Program that was the subject of considerable debate. Significant revision to Mifegymiso's approved use and distribution was issued by Health Canada on November 7, 2017.

The Nova Scotia College of Pharmacists provides the following guidance to pharmacists and pharmacy technicians when dispensing Mifegymiso® so that unnecessary barriers for patient access can be avoided and appropriate safeguards for patient safety are in place. For clarity, pharmacists in Nova Scotia are authorized to dispense but not to prescribe Mifegymiso.

Guidance

Health Canada's November 7, 2017 Information Update on Mifegymiso states that:

- Mifegymiso can now be prescribed up to nine weeks (63 days) into a pregnancy, rather than the previous limit of seven weeks (49 days).
- Mifegymiso can now be dispensed directly to patients by a pharmacist or a prescribing health professional. Directions for use remain the same. Patients should take the medication as directed by their health professional, either at a health facility or at home.
- While dialogue and information sharing between patients and health professionals is always important, the requirement for written patient consent to use Mifegymiso is being removed.
- Health professionals will no longer be required to register with Celopharma in order to prescribe or dispense Mifegymiso.

Collaboration

It is critical that in providing Mifegymiso® to patients, there is clear, interprofessional communication regarding the directions for consumption, and the responsibility and accountability for informed consent, counselling, assessment, monitoring and follow-up.

At a local level, pharmacists are encouraged to communicate with physicians in advance regarding whether they are willing and competent to participate in providing Mifegymiso® to patients. Participating practitioners must use a collaborative process that will ensure the care provided is patient-centered, does not create unnecessary barriers to access, and provides appropriate safeguards for patient safety.

Given the time-sensitive nature of medical abortion, pharmacies should have a plan in place that protects patients' rights to access high-quality health services while also upholding individual providers' rights to conscientious objection.

Competency

It is the professional responsibility of a pharmacist to ensure that they have the knowledge and skills required to competently dispense Mifegymiso®. The following educational resources are available to support the pharmacist in meeting this responsibility.

Resources

Accredited Medical Abortion Training Program, Society of Obstetricians and Gynaecologists of Canada, 2016

Additional resources for providers are available through Canadian Abortion Providers Support (CAPS):
https://www.caps-cpca.ubc.ca/index.php?title=Main_Page&oldid=36

Health Canada: [Information Update](#), [Health Professional Risk Communication](#), [Regulatory Decision Summary](#).

General product information and forms, Celopharma, Inc. www.celopharma.com



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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;



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- 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).



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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

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



DISPENSING MIFEGYMISO® ***Guidance for Pharmacy Professionals***

This document replaces “DISPENSING MIFEGYMISO® Guidance for Pharmacy Professionals” created November 16, 2017.

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. On November 7, 2017 Health Canada released updates regarding the [Mifegymiso® product monograph and the Risk Management Plan](#) as well as updates to [prescribing and dispensing information for Mifegymiso®](#). Subsequently on April 16, 2019 Health Canada approved updates to [Mifegymiso prescribing information: Ultrasound no longer mandatory](#). All updates are attached as appendices to this document for your information.

Recommendations

SCPP strongly recommends the following for pharmacists and pharmacy technicians involved in dispensing Mifegymiso®:

1. **Training:** Undertake the training as referenced in the documents (appendices) so that you are aware of the issues prescribers must consider in prescribing this product and of your support role in assisting prescribers and patients with optimizing the use of this product including after-care. The course is available to prescribers and pharmacists through the e-learning portal of the Society of Obstetricians and Gynecologists of Canada (SOGC). [SOGC Online Courses](#);
2. **Collaboration:** Before dispensing, collaborate with the prescriber and the patient to fully understand the treatment decisions that have been made between them for the product’s distribution and administration.

For further information contact SCPP at info@saskpharm.ca or at 306-584-2292.

Appendix A: MIFEGYMISO (mifepristone and misoprostol tablets) - Updates to Product Monograph and Risk Management Plan

(<http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2017/65030a-eng.php>)

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Recalls and safety alerts

Recalls & alerts | Kids | Food | Your Health | Environment | Consumer products

Home > Recalls & alerts

MIFEGYMISO (mifepristone and misoprostol tablets) - Updates to Product Monograph and Risk Management Plan

Starting date: November 7, 2017
Posting date: November 7, 2017
Type of communication: Dear Healthcare Professional Letter
Subcategory: Drugs
Source of recall: Health Canada
Issue: Product Safety
Audience: Healthcare Professionals
Identification number: RA-65030

[Report a Concern](#)

- [Issue](#)
- [Who is affected](#)
- [Report health or safety concerns](#)

Audience

Health professionals, including obstetricians/gynaecologists, family physicians, hospital pharmacy chiefs, pharmacists, nurses, and associations and Colleges of Canadian physicians, pharmacists, and nurses.

Key messages

This Health Product Risk Communication for MIFEGYMISO:

- **Informs about modifications to the product indication and steps to follow prior to prescribing MIFEGYMISO.**
- **Provides information on the modifications of the MIFEGYMISO product monograph and the Risk Management Plan including the Distribution and the Education Program.**
- **Highlights that in the currently distributed boxes, the Patient Information Card and package insert may not reflect the revised information found in the Product Monograph.**

Issue

Health Canada, in collaboration with Celopharma, is issuing this communication to health professionals to inform them about modifications to the MIFEGYMISO product monograph and the Risk Management Plan including extension of the indication and changes to the Distribution and Education Program in Canada. This is a [follow up to the communication issued on May 18, 2017](#).

Products affected

The product impacted is:			
Manufacturer	Distributor	Product	DIN
Linepharma International Limited	Celopharma Inc.	MIFEGYMISO (mifepristone 200 mg and misoprostol 200 mcg tablets)	02444038

Background information

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. On November 7th, 2017 Health Canada completed its review of a new submission to revise the indication, and update the Risk Management Plan. A summary of the information that supported these changes can be found in the [Regulatory Decision Summary](#).

Who is affected

Information for health professionals

Important modifications to MIFEGYMISO indication

MIFEGYMISO is now indicated for medical termination of a developing intra-uterine pregnancy with a gestational age up to nine weeks (63 days) as measured from the first day of the last menstrual period. The previous indication was for use up to seven weeks (49 days) as measured from the first day of the last menstrual period.

Important modifications for recommendations to Health professionals

Registration of health professionals with Celopharma is no longer required in order to prescribe or dispense MIFEGYMISO.

The MIFEGYMISO education program is not mandatory. However, MIFEGYMISO should be prescribed by health professionals with prior adequate knowledge of medical abortion and use of MIFEGYMISO or who have completed a MIFEGYMISO education program.

The Education Program is now available to all health professionals and, like other educational tools, is available on the Celopharma website and through some professional associations.

Mifegymiso can now be dispensed directly to patients by a pharmacist or a prescribing health professional. As was always the case, patients should take the medication as directed by their health professional, either at a health facility or at home.

Health professionals are required to do the following prior to prescribing MIFEGYMISO:

- Ensure you 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 the 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 administration of mifepristone; and,
- Schedule a follow-up 7 to 14 days after patients take mifepristone to confirm complete pregnancy termination and monitor for side effects.

Educational and information tools available

The following 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.

All tools, including the most recent Product Monograph, can be accessed from www.celopharma.com or by phone at 1-877-230-4227. In addition, the Patient Medication Information and Patient Information Card can be found inside the MIFEGYMISO box. The product monograph can also be accessed on the Health Canada website.

Information for consumers

MIFEGYMISO is a combination product containing two drugs (one mifepristone tablet (step 1) and four misoprostol tablets (step 2)) used for abortion, meaning ending a pregnancy within the first nine weeks.

Before getting MIFEGYMISO, your health professional will:

- Counsel you on the risks and benefits of MIFEGYMISO;
- Provide a printed copy of the Patient Medication Information, a document that provides detailed information on MIFEGYMISO;
- Provide a completed Patient Information Card;
- Ask for an ultrasound scan;
- Inform you and seek your consent to take the drug.

When completed, the Patient Information Card contains the following information:

- The date and time when to take mifepristone (step 1) and misoprostol tablets (step 2);
- The follow-up appointment date and time;
- Contact information in case you need to call your health professional or clinic;
- Where to go in case of an emergency.

Follow-up is important to confirm whether the pregnancy has completely ended and to verify that there is no prolonged heavy bleeding or infection.

Patients should contact a health professional if they experience a side effect related to MIFEGYMISO use or if they wish to obtain additional information on the use of MIFEGYMISO and its safety.

Currently distributed Mifegymiso boxes

Some Patient Information Cards and package inserts and boxes being distributed with the product may not reflect the **current** information of the revised Product Monograph until updated labelling is made available. Celopharma has committed to update these documents by summer 2018.

Other available resources

Celopharma's toll-free line [1-877-230-4227](tel:1-877-230-4227) will be available to provide general information to patients or health professionals on MIFEGYMISO.

Report health or safety concerns

Managing marketed health product-related side effects depends on health care professionals and consumers reporting them. Any cases of serious or unexpected side effects in patients receiving MIFEGYMISO should be reported to Celopharma or Health Canada.

You can report any suspected adverse reactions associated with the use of Mifegymiso to Celopharma Inc. by:

- E-mail at info@celopharma.com

To correct your mailing address or fax number, contact Celopharma Inc.

You can report any suspected adverse reactions associated with the use of health products to Health Canada by:

- Calling toll-free at [1-866-234-2345](tel:1-866-234-2345); or
- Visiting MedEffect Canada's Web page on [Adverse Reaction Reporting](#) for information on how to report online, by mail or by fax.

For other health product inquiries related to this communication, contact Health Canada at:

Marketed Health Products Directorate

E-mail: mhpd-dpsc@hc-sc.gc.ca

Telephone: [613-954-6522](tel:613-954-6522)

Fax: 613-952-7738

Original signed by

Paula Tenenbaum
President
Celopharma Inc.



For more information

The manufacturer advised Health Canada of the issue associated with this health product. Health Canada supports the actions taken by the manufacturer and as such a risk assessment was not required and a Summary Safety Review was not prepared.

Date modified: 2017-11-0

Appendix B: Health Canada updates prescribing and dispensing information for Mifegymiso (<http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2017/65034a-eng.php>)

The screenshot shows the Health Canada website page for a recall and safety alert regarding Mifegymiso. The page header includes the Government of Canada logo and navigation links for Services, Departments, and Français. The main heading is "Recalls and safety alerts" with a red maple leaf graphic. Below this is a navigation bar with categories: Recalls & alerts, Kids, Food, Your Health, Environment, and Consumer products. The main content area features the title "Health Canada updates prescribing and dispensing information for Mifegymiso" and a "Report a Concern" button. A table provides key details: Starting date (November 7, 2017), Type of communication (Information Update), Subcategory (Drugs), Source of recall (Health Canada), and Identification number (RA-65034). A list of links includes Issue, Public enquiries, What you should do, What industry professionals should do, Report health or safety concerns, and Media enquiries.

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Recalls and safety alerts

Recalls & alerts | Kids | Food | Your Health | Environment | Consumer products

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Health Canada updates prescribing and dispensing information for Mifegymiso

Starting date: November 7, 2017
Type of communication: Information Update
Subcategory: Drugs
Source of recall: Health Canada
Identification number: RA-65034

[Report a Concern](#)

- Issue
- Public enquiries
- What you should do
- What industry professionals should do
- Report health or safety concerns
- Media enquiries

Issue

OTTAWA – Health Canada is informing Canadians and health professionals of changes regarding the prescribing and dispensing of Mifegymiso.

Health Canada has received and rigorously reviewed new scientific evidence submitted by the drug sponsor, Linepharma (represented in Canada by Celopharma). The Department has also undertaken a thorough review of new and existing scientific literature on the safe use and effectiveness of Mifegymiso. This has formed the basis for the Department to authorize the following changes:

- Mifegymiso can now be prescribed up to nine weeks (63 days) into a pregnancy, rather than the previous limit of seven weeks (49 days).
- Mifegymiso can now be dispensed directly to patients by a pharmacist or a prescribing health professional. Directions for use remain the same. Patients should take the medication as directed by their health professional, either at a health facility or at home.
- Health professionals should have appropriate knowledge about the medication before prescribing Mifegymiso. Education programs are available. However, health professionals are no longer required to complete an education program before they can prescribe Mifegymiso.
- While dialogue and information sharing between patients and health professionals is always important, the requirement for written patient consent to use Mifegymiso is being removed.
- Health professionals will no longer be required to register with Celopharma in order to prescribe or dispense Mifegymiso.

The formulation of Mifegymiso itself has not changed. It remains a combination product containing two medications: mifepristone and misoprostol. These medications are used in sequence for the medical termination of a pregnancy. The changes being announced today apply only to use and product labelling.

Health professionals who want training on the use of Mifegymiso can obtain it from Celopharma and from national and provincial medical groups.

The Patient Medication Information, the Patient Consent Form and the Patient Information Card can be found on the Celopharma website at www.celopharma.com. In addition, the Patient Medication Information and the Patient Information Card can be found inside the Mifegymiso package.

The most recent Product Monograph can be accessed on the Health Canada website, or by contacting the company at www.celopharma.com or at 1-877-230-4227.

Health Canada continues to monitor the safety profile of Mifegymiso through its post-market surveillance program, to help ensure that the benefits of the product continue to outweigh the risks. Should any issues arise, Health Canada will act quickly to assess them and take appropriate action.

What you should do

- Before taking Mifegymiso, have a discussion with your health professional about informed consent as well as the medication's effects and risks.
- Obtain a printed copy of the Patient Information Card and the Patient Medication Information (a document that provides detailed information on the safe and effective use of Mifegymiso) from your health professional.
- Have an ultrasound to ensure that you don't have an ectopic (outside the uterus) pregnancy and to have an assessment of gestation.
- Take Mifegymiso as directed by your health professional.
- Follow up with your health professional in 7 to 14 days to confirm whether the pregnancy has completely ended and to verify that there is no prolonged heavy bleeding or infection.
- Contact a health professional if you experience any serious or unexpected side effects related to Mifegymiso use, or if you wish to obtain additional information.

What industry professionals should do

- Ensure that you 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 the patient on the effects and risks of Mifegymiso, including bleeding, infection, and incomplete pregnancy termination.
- Ensure that the patient has access to emergency medical care in the 14 days following administration of mifepristone.
- Schedule a follow-up to occur 7 to 14 days after the patient takes mifepristone to confirm complete pregnancy termination and to monitor for side effects.

Report health or safety concerns

To report a side effect to a health product to Health Canada:

- Call toll-free at [1-866-234-2345](tel:1-866-234-2345)
- Visit Health Canada's Web page on [Adverse Reaction Reporting](#) for information on how to report online, by mail or by fax.

Media enquiries

Health Canada
[613-957-2983](tel:613-957-2983)

Public enquiries

[613-957-2991](tel:613-957-2991)
[1-866-225-0709](tel:1-866-225-0709)



For more information

- [MIFEGYMISO \(mifepristone and misoprostol tablets\) - Updates to Product Monograph and Risk Management Plan](#)

Stay connected with Health Canada and receive the latest advisories and product recalls using [social media](#) tools.

Date modified: 2017-11-07

Appendix C: Health Canada approves updates to Mifegymiso prescribing information: Ultrasound no longer mandatory (<http://healthy Canadians.gc.ca/recall-alert-rappel-avis/hc-sc/2019/69620a-eng.php>)

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Recalls and safety alerts

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Health Canada approves updates to Mifegymiso prescribing information: Ultrasound no longer mandatory

Starting date:	April 16, 2019
Type of communication:	Information Update
Subcategory:	Drugs
Source of recall:	Health Canada
Identification number:	RA-69620

Last updated: 2019-04-16

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Report a Concern

OTTAWA – Health Canada is informing Canadians that the prescribing and patient information for Mifegymiso has been updated to reflect that an ultrasound is no longer required before the drug is prescribed. Mifegymiso is a combination product containing two drugs (mifepristone and misoprostol) that are taken in sequence for the medical termination of a pregnancy.

Previously, the Canadian product monograph for Mifegymiso indicated that an ultrasound was required before prescribing Mifegymiso to confirm the gestational age (number of weeks pregnant) and to rule out an ectopic pregnancy (a pregnancy outside the womb).

With the changes to the product monograph, prescribers now have the flexibility to use their medical judgement on how best to determine the gestational age and to rule out an ectopic pregnancy. It also responds to concerns that some patients may have been facing unnecessary barriers or delays in accessing this product. The product monograph still recommends an ultrasound when the gestational age is uncertain or an ectopic pregnancy is suspected.

Health Canada based its decision on a review of the information submitted by the company (Linepharma International Limited, which is represented in Canada by Celopharma Inc.), the most recent scientific literature, and experience with the use of the product internationally.

As outlined in the product monograph, Mifegymiso should not be prescribed to patients who are more than nine weeks (63 days) pregnant or have an ectopic pregnancy. Under these conditions, the drug may not successfully terminate the pregnancy, may damage the fetus, and can result in serious health risks to the pregnant woman. The use of Mifegymiso could mask a ruptured ectopic pregnancy as the symptoms associated with both may be similar.

As part of the update, the product monograph now includes the 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 (see links below for previous changes communicated in November 2017). The latest version of the Mifegymiso [product monograph](#) is available on Health Canada's website.

Health Canada has asked the company to monitor the risks related to potential inaccurate pregnancy dating and missed ectopic pregnancy diagnoses, and to notify Health Canada should these safety concerns arise. Health Canada will act quickly to take appropriate action should safety concerns emerge.

Health Canada continues to monitor the safety of Mifegymiso through its post-market surveillance program to help ensure that the benefits of the product continue to outweigh the risks.

Report health or safety concerns

To report a side effect to a health product to Health Canada:

- Call toll-free at 1-866-234-2345
- Visit Health Canada's Web page on [Adverse Reaction Reporting](#) for information on how to report online, by mail or by fax.

Media enquiries

Health Canada

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Public enquiries

(613) 957-2991

1-866 225-0709



For more information

- [Canadian product monograph for Mifegymiso](#)
- November 17, 2017, Dear Healthcare Professional Letter: [MIFEGYMISO \(mifepristone and misoprostol tablets\) - Updates to Product Monograph and Risk Management Plan](#)
- November 17, 2017, Information for consumers: [Health Canada updates prescribing and dispensing information for Mifegymiso](#)
- May 17, 2017, Dear Healthcare Professional Letter: [MIFEGYMISO \(mifepristone and misoprostol tablets\) - Canadian Distribution and Administration Program](#)

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1. Newfoundland and Labrador.

The Pharmacists' Role in the provision of Mifegymiso

<https://nlpb.ca/news-advisories/nlpb-news/the-postscript-archives-2019/>

2. British Columbia

<https://www.bcpharmacists.org/mifegymiso>