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.

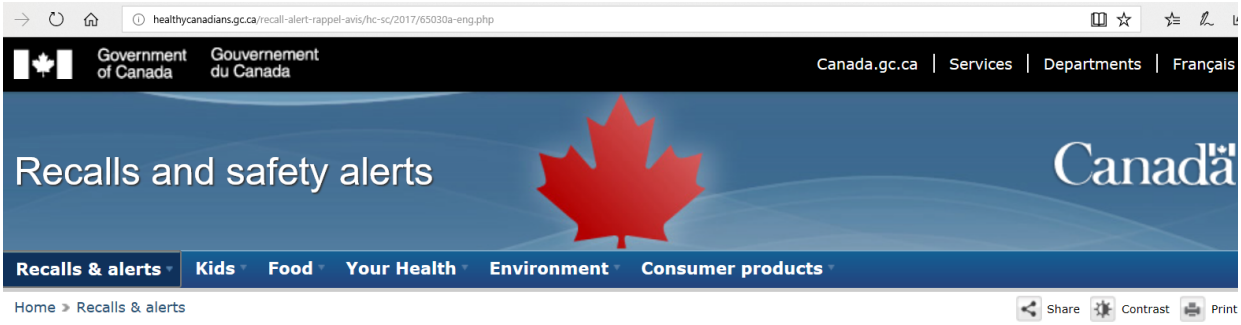
For further information contact SCPP at info@saskpharm.ca or at 306-584-2292.

Questions?
info@saskpharma.ca

Created: Aug 29, 2017
Revised: April 18, 2019

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)



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 chose 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 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; 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
Fax: 613-952-7738

Original signed by

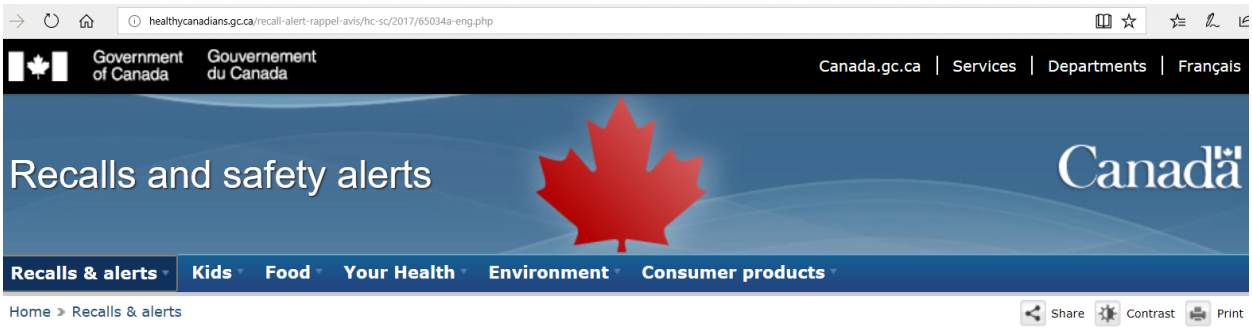
Paula Tenenbaum
President
Celopharma Inc.

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)



healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2017/65034a-eng.php

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

Public enquiries

613-957-2991
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://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2019/69620a-eng.php)

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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

Report a Concern

Last updated: 2019-04-16

- Report health or safety concerns
- Media enquiries
- Public enquiries

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
(613) 957-2983
hc.media.sc@canada.ca

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

Stay connected with Health Canada and receive the latest advisories and product recalls using social media tools.