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

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.

What is the 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 (available at: http://healthy.canadians.gc.ca/recall-alert-rappel-avis/hc-sc/2017/63330a-eng.php).

Products affected

<table>
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<tr>
<th>Manufacturer</th>
<th>Distributor</th>
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<tr>
<td>Linepharma International Limited</td>
<td>Celopharma Inc.</td>
<td>MIFEGYMISO (mifepristone 200 mg and misoprostol 200 mcg tablets)</td>
<td>02444038</td>
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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.

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 ([https://health-products.canada.ca/dpd-bdpp/index-eng.jsp](https://health-products.canada.ca/dpd-bdpp/index-eng.jsp)).

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 (http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) 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

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