Mifegymiso

Information for the prescribing physician

Updated April 25, 2019

Health Canada approved the use of Mifegymiso for the medical termination of a developing intrauterine pregnancy with a gestational age up to nine weeks (63 days) as measured from the first day of the last menstrual period in a presumed 28-day cycle.

Health Canada considered the potential risks associated with Mifegymiso's conditions of use and the pharmaceutical company Linepharma International Limited agreed to implement the following post-authorisation commitments to ensure the safe use of this product:

- a Restrictive Distribution and Administration Program;
- a Canadian Phase IV observational study of Mifegymiso safety;
- a 24 Hour support line in both English and French for patients taking Mifegymiso.

Health Canada has determined that prior to prescribing Mifegymiso physicians must:

1. ensure you have adequate knowledge of the use of trhese medications to prescribe Mifegymiso;

2. discuss **informed consent** with the patient and provide the patient with a printed copy of the current **Patient Medication Information** and a completed **Patient Information Card**;

3. exclude ectopic pregnancy and confirm gestational age by an appropriate method. An ultrasound is recommended when the gestational age is uncertain or an ectopic pregnancy is suspected.

4. counsel each patient on the risks and benefits of the Mifegymiso, including bleeding, infection and incomplete abortion;

5. ensure that patients have access to emergency medical care in the 14 days following administration of Mifepristone;

6. schedule follow-up 7 to 14 days after patients take the Mifepristone to confirm complete pregnancy termination.

Mifegymiso is a medication that has potential risks. The need for medical supervision is based on what Health Canada deems as "the strong evidence of good health and safety outcomes." The patient must be seen and physically examined and followed up as per the requirements.

Linepharma has developed an educational program for physicians to ensure safe and effective use of Mifegymiso. This program is recommended by the CPSS.

The information we have received with respect to the restricted distribution program is as follows:

1. patients can take the prescription to a pharmacist of their choice and have the drug delivered to the physician's office to take, which is consistent with the product monograph; or,

2. Mifegymiso can 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.

Physicians and other prescribers wishing to seek additional clarification on this medication can refer to:

Health Canada Healthcare Professional Letters
April 16, 2019 update (https://tinyurl.com/y6hkbtff)
Nov 17, 2017 update (https://tinyurl.com/y6bkozs6)
May 17, 2017 (https://tinyurl.com/yyp79ets)

Product Monograph
https://pdf.hres.ca/dpd_pm/00050659.PDF

Saskatchewan Drug Formulary
http://www.saskatchewan.ca/government/news-and-media/2017/august/31/mifegymiso-added-to-formulary

Saskatchewan College of Pharmacy Professionals Dispensing Guidelines
https://scp.in1touch.org/document/3692/Mifegymiso_Dispensing_Gdlns_20170829.pdf