



Canadian Physicians
for *Life*

Canadian Physicians for Life on

RU-486 in Canada

Introduction

Health Canada has approved Linepharma International Limited's application to sell RU-486 after approximately three years of consideration.¹ RU-486 is a two drug combination that terminates pregnancies within 49 days of the beginning of a woman's last menstrual period.² There is a distinction between the effect of the "morning-after" pill and RU-486. The "morning-after" pill prevents or delays ovulation, prevents fertilization or prevents implantation of the fertilized egg.³ RU-486 prevents development after implantation of the fertilized egg in the uterine lining.⁴ The effect of RU-486 is to produce a process similar to that of a miscarriage.⁵

How RU-486 works

RU-486 is comprised of mifepristone, which blocks the effects of the hormone (progesterone) required to maintain the uterine lining, and misoprostol, which causes uterine contractions that lead to the expulsion of the contents of the uterus.⁶ A patient would take mifepristone on day one and then take the misoprostol 24 to 48 hours later.⁷ The average patient will experience approximately 10.8 days of bleeding.⁸ The drug fails to completely terminate a pregnancy 2% - 4.8% of the time.⁹

RU-486 reversals

Research indicates that it is possible to reverse the process of RU-486 induced abortion by injecting the mother with progesterone, but it must be done before misoprostol is taken.¹⁰ Since misoprostol is scheduled to be taken on the third day, the timeframe for administering progesterone for a successful result is short.

Known side effects of RU-486

Potential known side effects of RU-486 are vaginal bleeding, diarrhea, nausea, vomiting, headache, dizziness, back pain, and tiredness.¹¹ Severe infection (sepsis) is a risk associated with any form of abortion, and there have been eight reported deaths from sepsis of women who used RU-486.¹² In four cases, the woman took the second drug intravaginally.¹³ A Canadian woman also died of septic shock after taking RU-486 in a clinical trial.¹⁴ The FDA has only approved oral use of the drug. However, medical literature reveals that practitioners are following a variety of regimens for the drug.¹⁵

Existing medical abortion option in Canada

An alternate medical abortion is currently available in Canada – a two drug process involving methotrexate and misoprostol.¹⁶ This form of medical abortion is reputed to be inferior to RU-486, reportedly being less effective and resulting in a longer time period



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between taking the drugs and completion of the abortion.¹⁷ However, there is a study that suggests that, while RU-486 is a faster process, the effectiveness and health risks of both forms of medical abortion are similar.¹⁸

RU-486 advocated for women in rural areas

Proponents of the drug want to bring RU-486 to the Canadian market in order to increase abortion access for women living in rural areas where surgical abortions aren't available.¹⁹ However, women who experience heavy vaginal bleeding after using RU-486 would need to undergo surgical procedures.²⁰ There were approximately 116 cases in the US between 2000 and 2006 in which women required a blood transfusion after experiencing heavy bleeding.²¹

RU-486 in Canada

RU-486 will be sold in Canada, through Celopharma Inc, under the name "Mifegymiso".²² The drug will probably not be available on the Canadian market before early 2016.²³ Mifegymiso will be sold as a two package kit; a green box will contain the first drug, mifepristone, and an orange box will contain the second drug, misoprostol.²⁴ Patients will be required to sign a consent form and will need a prescription from a physician to obtain the Mifegymiso.²⁵

¹¹ Raj, Althia. "Health Canada Oks Use of RU-486 Abortion Pill." Huffington Post.

² U.S. Food and Drug Administration. "Mifeprex (mifepristone) Information." Accessed July 16, 2015.

³ Ziemann, Mimi. "Emergency contraception." UpToDate. Accessed July 23, 2015. Paladin Labs Inc. "How does the Plan B morning after pill work?" Accessed August 18, 2015.

⁴ Delgado, George, and Mary L. Davenport. "Progesterone Use to Reverse the Effects of Mifepristone." The Annals of Pharmacotherapy. Accessed July 16, 2015.

⁵ Kirkey, Sharon. "Approve abortion pill mifepristone, doctors group urges Health Canada." National Post.

⁶ Danco Laboratories. "What is Mifeprex?" <http://earlyoptionpill.com/what-is-mifeprex/>. Accessed July 16, 2015.

⁷ Harwood, Bryna. "First trimester medical abortion (termination of pregnancy)." UpToDate. Accessed July 23, 2015.

⁸ Health Canada. "Regulatory decision summary: MIFEGYMISO." Accessed July 30, 2015.

⁹ Health Canada. "Regulatory decision summary: MIFEGYMISO." Accessed July 30, 2015.

¹⁰ Delgado, George, and Mary L. Davenport. "Progesterone Use to Reverse the Effects of Mifepristone." The Annals of Pharmacotherapy. Accessed July 16, 2015.

¹¹ U.S. Food and Drug Administration. "Mifeprex Questions and Answers." Accessed July 16, 2015.

¹² U.S. Food and Drug Administration. "Mifeprex Questions and Answers." Accessed July 16, 2015.

¹³ U.S. Food and Drug Administration. "Mifepristone: Approval Process and Postmarketing Activities." Accessed July 16, 2015.

¹⁴ U.S. Food and Drug Administration. "Mifepristone: Approval Process and Postmarketing Activities." Accessed July 16, 2015.

¹⁵ U.S. Food and Drug Administration. "Mifepristone: Approval Process and Postmarketing Activities." Accessed July 16, 2015.

¹⁶ Cook, Rebecca, and Sheila Dunn. "Medical abortion in Canada: behind the times." CMAJ. Accessed July 17, 2015.

¹⁷ Harwood, Bryna. "First trimester medical abortion (termination of pregnancy)." UpToDate. Accessed July 23, 2015.

¹⁸ Wiebe, E et al. "Comparison of abortions induced by methotrexate or mifepristone followed by misoprostol." Obstetrics and Gynecology. Accessed July 17, 2015.



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¹⁹ Kane, Laura. "Health Canada urged to approve abortion drug RU-486." The Toronto Star.

²⁰ U.S. Food and Drug Administration. "Mifeprex Questions and Answers." Accessed July 16, 2015.

²¹ U.S. Food and Drug Administration. "Mifepristone: Approval Process and Postmarketing Activities." Accessed July 16, 2015.

²² Medical/Pharmaceuticals. "Health Canada Approves Mifegymiso™, the First Drug Indicated for Medical Abortion." Canada NewsWire.

²³ Medical/Pharmaceuticals. "Health Canada Approves Mifegymiso™, the First Drug Indicated for Medical Abortion." Canada NewsWire.

²⁴ Raj, Althia. "Health Canada Oks Use of RU-486 Abortion Pill." Huffington Post.

²⁵ Health Canada. "Regulatory decision summary: MIFEGYMISO." Accessed July 30, 2015.