



PUBLIC COMMUNICATION
Health Canada Endorsed Important Safety Information on
MIRENA[®]

June 15, 2010

Subject: Association of MIRENA[®] (Levonorgestrel-releasing Intrauterine System) with the potential risk of uterine perforation

Bayer Inc., in collaboration with Health Canada, wishes to inform about important safety information regarding reports of uterine perforation in women treated with MIRENA[®].

MIRENA[®], a therapeutic intrauterine system, is authorized in Canada for prevention of pregnancy and treatment of heavy menstrual bleeding. Uterine perforation is a rare complication associated with all intrauterine contraceptive devices/systems, including MIRENA[®]. Perforation occurs at a rate between 1/1,000 and 1/10,000 insertions. Bayer Inc. continues to receive reports of uterine perforation associated with the use of MIRENA[®]. The risk of perforation may be increased after pregnancy, during lactation, and in women with atypical uterine anatomy. Uterine perforation may occur as MIRENA[®] is being inserted or after the insertion with limited symptoms. In order to reduce the risk of uterine perforation and associated complications, you should consider the following recommendations:

- Ask your doctor if MIRENA[®] is right for you.
- Tell your doctor the timing of your last pregnancy and whether you are currently breastfeeding.
- Ask your doctor on how to identify possible signs of uterine perforation. This may include, but is not limited to severe lower abdominal pain which may be accompanied with bleeding. Ask your doctor how you can check that the removal threads of MIRENA[®] are still in place.
- Re-visit your doctor within 4 to 12 weeks after insertion, and once-a-year thereafter.

MIRENA[®] works by slowly releasing levonorgestrel directly into the uterus to prevent pregnancy and to treat heavy menstrual bleeding. Levonorgestrel is a hormone commonly used in combination oral contraceptives.

Bayer Inc., in collaboration with Health Canada, issued a letter to Canadian Health Care Professionals reminding them of this important safety information which is part of the current MIRENA[®] Product Monograph. A copy of that letter is available on the Health Canada web site (http://hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/_2010/index-eng.php).

For more information about MIRENA[®], patients should consult their doctor or refer to the patient information document available on the Bayer Web site at <http://www.bayer.ca/?q=en/node/62>.



Managing marketed health product-related adverse reactions depends on health care professionals and consumers reporting them. Reporting rates determined on the basis of spontaneously reported post-marketing adverse reactions are generally presumed to underestimate the risks associated with health product treatments. Any case of uterine perforation or other serious or unexpected adverse reactions in patients receiving MIRENA[®] should be reported to Bayer Inc. or Health Canada at the following addresses:

Bayer Inc.
77 Belfield Road
Toronto, Ontario
M9W 1G6
Toll-free telephone: 1-800-265-7382
E-mail: Canada.medinfo@bayer.com

Any suspected adverse reaction can also be reported to:

Canada Vigilance Program
Marketed Health Products Directorate
HEALTH CANADA

Address Locator: 0701C
Ottawa, Ontario, K1A 0K9
Tel: 613-957-0337 or Fax: 613-957-0335

To report an Adverse Reaction, consumers and health professionals may call toll free:

Tel: 866-234-2345

Fax: 866-678-6789

CanadaVigilance@hc-sc.gc.ca

The [AR Reporting Form](#) and the [AR Guidelines](#) can be found on the Health Canada web site or in *The Canadian Compendium of Pharmaceuticals and Specialties*.

http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/form/ar-ei_form_e.html

http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/guide/ar-ei_guide-ldir_e.html

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

Marketed Health Products Directorate

E-mail: mhpd_dpsc@hc-sc.gc.ca

Tel: 613-954-6522

Fax: 613-952-7738

Sincerely,

A handwritten signature in black ink, appearing to read "S. Choudhri".

Shurjeel Choudhri, MD FRCPC
Senior Vice President & Head, Medical & Scientific Affairs
Bayer HealthCare Pharmaceuticals

References:

1. MIRENA Product Monograph, May 11, 2010.