



PUBLIC COMMUNICATION
HEALTH CANADA ENDORSED IMPORTANT SAFETY INFORMATION
REGARDING EVRA* (norelgestromin and ethinyl estradiol) Transdermal System

SUBJECT: New safety information about EVRA* (norelgestromin and ethinyl estradiol) Transdermal System

Janssen-Ortho Inc., in consultation with Health Canada, wishes to highlight important new safety information pertaining to EVRA*. The EVRA* transdermal system marketed in Canada contains 6.0 mg norelgestromin (NGMN) and 0.60 mg ethinyl estradiol (EE) and is approved for use in contraception (prevention of pregnancy). ORTHO EVRA[®] is the formulation of EVRA* marketed in the United States and contains 6.0 mg NGMN and 0.75mg EE. Although EVRA* and ORTHO EVRA[®] are manufactured differently and therefore contain different total amounts of estrogen, the risk of side effects reported for ORTHO EVRA[®] is considered to apply equally to the EVRA* formulation available in Canada.

- **The results of a recent study indicate that women using the ORTHO EVRA contraceptive patch (the formulation of EVRA marketed in the United States) had an increased risk of blood clots in the legs and lungs compared to women using an oral contraceptive. Another study indicated no difference in the risk of blood clots in the legs and lungs in women using ORTHO EVRA compared to women using an oral contraceptive.**
- **Women who are obese are at particularly high risk of blood clots.**
- **Due to a theoretical risk of unintentional increase in estrogen exposure from the patch, patients are recommended not to expose the patch area to sources of heat such as sauna or whirlpool bath.**
- **A recent study showed that the EVRA transdermal system sold in Canada produced a similar total estrogen exposure in patients compared to taking a typical birth control pill.**

The current Canadian labeling information on EVRA contains a description of the risks and proper use of the product. There is also a detailed section on the importance of discontinuing the medication at the earliest sign of blood clots. Common symptoms of blood clots can include, but are not limited to, pain the calf, shortness of breath, chest pain or coughing blood. Patients concerned about the risks and benefits of EVRA should speak to their physician.

Janssen-Ortho Inc. has provided this information to physicians, nurses and pharmacists across Canada.

This advisory and letters issued to physicians, nurses and pharmacists can be accessed at Health Canada's website at: http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/index_e.html

This information is also available at <http://www.janssen-ortho.com>. For more information, patients should consult their health care professional. Patients should NOT discontinue their medication without consulting their physician or pharmacist first. If you have questions about EVRA, please talk to your doctor or take the medication back to your pharmacy and speak to your pharmacist.

For further information on Janssen-Ortho Inc.: call Suzanne Frost, Janssen-Ortho Inc., (416) 449-9444 or call the Janssen-Ortho Medical Information Department at 1-800-567-3331, from 9 a.m. to 5 p.m. Monday to Friday, EST.

The identification, characterization, and management of marketed health product-related adverse reactions are dependent on the active participation of health care professionals in adverse drug reaction reporting programmes. Any occurrences of serious and/or unexpected adverse reactions in patients receiving EVRA, including cases of fatality or blood clots, should be reported to Janssen-Ortho Inc. or the Marketed Health Products Directorate at the following addresses:

Janssen-Ortho Inc.
19 Green Belt Drive
Toronto, Ontario
M3C 1L9
Or call toll-free at 1-800-567-3331
Or email to dsscan@joica.jnj.com
Or toll-free fax to 1-866-767-5865

Any suspected adverse reaction can also be reported to:

Canadian Adverse Drug Reaction Monitoring Program (CADRMP)
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

cadrmp@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*.

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

Bureau of Metabolism, Oncology and Reproductive Sciences (BMORS)

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

Tel: (613) 941-3171

Fax: (613) 941-1365