Advisory

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For immediate release

Health Canada advises consumers of new warning For DIANE-35

OTTAWA - Health Canada is advising consumers of important information about the use of the prescription drug DIANE-35. Berlex and Health Canada reached an agreement on a new version of the Product Monograph. DIANE-35 is used for the treatment of women suffering from pronounced forms of acne. The drug should not be promoted nor used as a method of birth control.

The new patient package insert includes the following information:

- DIANE-35, as with all estrogen/progestogen combinations must not be used in women with thrombophlebitis, thromboembolic disorders (blood clots), or a history of these conditions.
- DIANE-35 users appear to have an elevated risk of blood clots compared to users of combination oral contraceptives in some published studies.
- DIANE-35 should not be prescribed for the purpose of birth control alone.
- Oral contraceptives should not be taken during treatment with DIANE-35.
- DIANE-35 should be discontinued 3 to 4 months after signs of acne have completely resolved.
- Consumers should be aware that cigarette smoking increases the risk of serious adverse effects on the heart and blood vessels from DIANE-35 use. This risk increases with age and heavy smoking (15 or more cigarettes a day) and is more marked in women over 35-years of age. Women who use estrogen/progestogen combinations should not smoke.

Patients should inform their doctor if they have or have had blood clots in the legs, lungs, eyes or elsewhere, or a stroke, heart attack, or chest pain.

The identification, characterization, and management of marketed health product-related adverse reactions are dependent on the active participation of health care professionals in adverse reaction reporting programmes. Any occurrences of thromboembolic disorders (blood clots) or other serious and/or unexpected adverse reactions in patients receiving DIANE-35® should be reported to Health Canada at the following address:

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

For other inquiries: please refer to contact information.

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*.

- Report of Suspected Adverse Reaction due to Health Products Marketed in Canada (Vaccines excluded)
- Canadian Adverse Drug Reaction Monitoring Program (CADRMP) Guidelines for the Voluntary Reporting of Suspected Adverse Reactions to Health Products by Health Professionals and Consumers

Media Inquiries:
Media Relations
Health Canada
(613) 957-2983

Public Inquiries:
(613) 957-2991

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