April 10,2003

PUBLIC ADVISORY - DIANE®-35 AND THE RISK OF VENOUS THROMBOEMBOLISM

Berlex Canada Inc. wants to inform Canadians about the risk of venous thromboembolism (blood clots) associated with the use of the prescription drug Diane®-35.

Based on an analysis, commissioned by Berlex, of recently published information, users of Diane®-35 appear to have an elevated risk of venous thromboembolic events compared to users taking low-dose combination oral contraceptives in some studies. This safety information has been provided to health care professionals to review with patients prior to prescribing Diane®-35. Diane®-35 should not be taken for the purpose of contraception alone. During treatment with Diane®-35, other oral contraceptives should not be used. Anyone taking Diane®-35 should discuss this safety information with their physician.

Patients who are taking Diane®-35 should immediately report to their doctor any of the following symptoms (which may indicate a possible blood clot): sharp pain in the chest, coughing blood, or sudden shortness of breath; pain in the calf; crushing chest pain or heaviness; sudden severe headache or vomiting, dizziness or fainting, disturbance of vision or speech, or weakness or numbness in an arm or leg; sudden partial or complete loss of vision.

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.

Diane®-35 is a medication for the treatment of women suffering from conditions caused by an increased amount or increased sensitivity to androgens (male hormones), such as pronounced forms of acne, especially those which are accompanied by seborrhea (excess oily secretions of the skin), inflammation or formation of nodes, and mild forms of hirsutism (excess hair on the face, chest, abdomen or legs), and for whom treatment with oral antibiotics or other available treatments has not worked. Diane®-35 is taken in tablet form.

Suspected adverse reactions concerning Diane®-35 can be reported directly to Berlex Canada Inc. or to Health Canada at the following addresses:

Berlex Canada Inc.
334 Avro Avenue
Pointe-Claire, Quebec
H9R 5W5
Tel: (800) 361-0240 or by fax at (514) 631-4721

Egalement disponible en français

For further information: Media Inquiries: Berlex Canada Inc.: 1-800-361-0240

original signed by

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Berlex Canada Inc.

Any suspected adverse reactions can also be reported to:

Canadian Adverse Drug Reaction Monitoring Program (CADRMP)
Marketed Health Products Directorate
HEALTH CANADA
Address Locator: 0201C2
OTTAWA, Ontario, K1A 1B9
Tel: (613) 957-0337 or Fax: (613) 957-0335
Toll free for consumers and health professionals:
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 TPD web site or in *The Canadian Compendium of Pharmaceuticals and Specialties*.