PUBLIC ADVISORY
IMPORTANT SAFETY INFORMATION REGARDING GLUCONORM® (REPAGLINIDE) AND GEMFIBROZIL AND THE RISK OF SEVERE AND PROLONGED HYPOGLYCEMIA

July 18, 2003 - Novo Nordisk Canada Inc. is informing Canadians that the simultaneous use of GlucoNorm® (repaglinide), an oral antidiabetic agent for type 2 diabetes, and gemfibrozil, a lipid-lowering agent, may carry serious risks. When GlucoNorm® (repaglinide) and gemfibrozil are taken together, patients may be at risk of severe and prolonged hypoglycemia (low blood sugar), a condition that is potentially fatal. Patients being treated with GlucoNorm® (repaglinide) should not start taking gemfibrozil. Patients already taking gemfibrozil should discontinue the use of this drug before taking GlucoNorm® (repaglinide). These decisions should be discussed with your treating physician.

Recently published results of a clinical study of healthy volunteers who were given both GlucoNorm® (repaglinide) and gemfibrozil show an adverse interaction between the two medications. When taken together with gemfibrozil, the blood glucose-lowering effect of GlucoNorm® (repaglinide) was described as considerably enhanced and prolonged. Novo Nordisk Canada Inc. has also received 5 reports (3 from the U.S. and 2 from France) of severe hypoglycemia in patients who were taking GlucoNorm® (repaglinide) and gemfibrozil simultaneously. No Canadian reports have been received.

Gemfibrozil is sold under the trade name Lopid®, as well as in generic form under other names. Patients should check their medication packaging to determine if they are taking gemfibrozil, or ask their pharmacist.

Patients should immediately inform their doctor if they are taking GlucoNorm® (repaglinide) and gemfibrozil in combination and alternative combination treatment should be instituted under close monitoring of diabetic status. They should seek medical attention immediately if they have any of the following symptoms that may indicate possible hypoglycemia: weakness, drowsiness, confusion, hunger, dizziness, paleness, headache, irritability, trembling, sweating, rapid heartbeat, and a cold, clammy feeling.

This safety information has been provided to health care professionals to review with patients prior to prescribing GlucoNorm® (repaglinide). This safety information will be added to the Canadian Product Monograph for Gluconorm® (repaglinide).

Suspected adverse reactions arising from the concomitant use of GlucoNorm® (repaglinide) and gemfibrozil can be reported directly to Novo Nordisk Canada Inc. at the following address:

Novo Nordisk Canada Inc.
c/o Medical and Scientific Affairs Department
2700 Matheson Blvd. East
3rd Floor, West Tower
Mississauga, Ontario
L4W 4V9
Toll: 1-800-465-4334
Tel: 905-629-4222

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*.