



The Marketed Health Products Directorate (MHPD), Therapeutic Products Directorate (TPD) and Biologics and Genetic Therapies Directorate (BGTD) post safety alerts, public health advisories, press releases and other notices from industry as a service to health professionals, consumers, and other interested parties. Although MHPD, TPD and BGTD approve therapeutic products, MHPD, TPD and BGTD do not endorse either the product or the company. Any questions regarding product information should be discussed with your health professional.

This is duplicated text of a letter from **Berlex Canada Inc.**  
Contact the company for a copy of any references, attachments or enclosures.



BERLEX CANADA INC

October 30, 2002

**IMPORTANT SAFETY INFORMATION REGARDING REFLUDAN®**

Dear Health Care Professional(s),

The purpose of this communication is to inform you of clinically important safety information regarding REFLUDAN® [lepirudin (rDNA) for injection]

REFLUDAN® is indicated for anticoagulation in adult patients with acute coronary syndromes (ACS); i.e. unstable angina/acute myocardial infarction without ST elevation. In patients with ACS, REFLUDAN® is intended for use with ASA. REFLUDAN® is also indicated for anticoagulation in patients with heparin induced thrombocytopenia (HIT) and associated thromboembolic disease in order to prevent further thromboembolic complications.

The following safety information reflects recent post-marketing experience with the product:

- **Cases of allergic and hypersensitivity reactions, including anaphylaxis, have been reported during initial administration or upon second or subsequent exposure. In rare instances, shock and death have been reported.**

**Rare cases of intracranial bleeding in the absence of concomitant thrombolytic therapy have been reported following REFLUDAN administration.**

Berlex Canada Inc is committed to providing you with the most current product safety information on its products and routinely assesses safety information and updates Product Monographs accordingly. Revised prescribing information will be distributed once approved by Health Canada. We hope this information will be helpful to you in caring for your patients on REFLUDAN®. Please consult the official REFLUDAN Product Monograph for complete prescribing information

The identification, characterization, and management of drug-related adverse events are dependent on the active participation of health care professionals in adverse drug reaction reporting programmes. Health care professionals are asked to report any suspected adverse reactions in patients receiving REFLUDAN® directly to Berlex Canada Inc. at the following address:

Berlex Canada Inc.  
2260 32<sup>nd</sup> Ave.  
Lachine, Quebec  
H8T 3H4  
Tel: (800) 361-0240 or by fax at (514) 631-4721

If you have any questions regarding REFLUDAN®, please contact Berlex Canada at (800) 361-0240.

Sincerely,

***original signed by*** \_\_\_\_\_

Dr. François Charette  
Vice-President, ScientificAffairs  
Berlex Canada Inc.

2260, 32<sup>e</sup> Avenue, Lachine (Québec) H8T 3H4  
Tél : (514) 631-7400 Fax : (514) 636-9177 [www.berlex.ca](http://www.berlex.ca)

**Any suspected adverse drug 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](mailto:cadrmp@hc-sc.gc.ca)

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