

**PUBLIC COMMUNICATION**

**Health Canada Endorsed Important Safety Information on  
Cerezyme® (imiglucerase for injection)**



December 21, 2009

**Subject: Cerezyme® (imiglucerase for injection) Supply and Recommendations for Restarting Cerezyme**

Cerezyme is used to treat patients with a confirmed diagnosis of non-neuronopathic (Type 1) or chronic neuronopathic (Type 3) Gaucher disease resulting in one or more of the following conditions:

- anaemia
- low platelet count
- bone disease
- enlarged liver or spleen

As a result of an interruption in production, Genzyme Canada advised the Canadian Gaucher community on June 29, 2009 of a treatment guidance designed to conserve the supply of Cerezyme in order to protect the most vulnerable patients. This guidance was established by the international Cerezyme Stakeholders Working Group (a group of Gaucher community stakeholders including medical experts and patient advocates).

In January 2010, Genzyme Canada will begin shipping Cerezyme to all Canadian patients who have had to stop receiving their Cerezyme treatment. Genzyme will fulfill orders one infusion at a time for each patient. Healthcare providers have been informed of this and provided with recommendations for resuming treatment. Patients should contact their doctors to arrange to restart treatment in 2010. Your doctor should determine how and where to restart Cerezyme based on your present condition and how you have tolerated Cerezyme® infusions in the past. For some patients with a history of infusion reactions, this may imply restarting Cerezyme in a hospital or clinic setting.

Managing marketed health product-related adverse reactions depends on healthcare professionals and consumers reporting them. Reporting rates determined on the basis of spontaneously reported post-marketing adverse reactions are generally presumed to underestimate the risks associated with health product treatments. Any case of serious reactions related to restarting infusions of CEREZYME or other serious or unexpected adverse reactions in patients receiving CEREZYME should be reported to Genzyme Canada Inc or Health Canada at the following addresses:

Genzyme Canada Inc.  
800-2700 Matheson Blvd. East  
Mississauga, Ontario L4W 4V9  
Tel: 905-625-0011  
Fax: 905-625-7811

**Any suspected adverse reaction can also be reported to:**

Canada Vigilance Program  
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

[CanadaVigilance@hc-sc.gc.ca](mailto:CanadaVigilance@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*.

[http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/form/ar-ei\\_form\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/form/ar-ei_form_e.html)

[http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/guide/ar-ei\\_guide-ldir\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/guide/ar-ei_guide-ldir_e.html)

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

Marketed Health Products Directorate (MHPD)

E-mail: [mhpd\\_dpdc@hc-sc.gc.ca](mailto:mhpd_dpdc@hc-sc.gc.ca)

Tel: 613-954-6522

Fax: 613-952-7738

For any additional information, please contact Genzyme Medical Information at 1-800-745-4447 or [medinfo@genzyme.com](mailto:medinfo@genzyme.com).

Sincerely,

*original signed by*

Brian Lewis  
General Manager  
Genzyme Canada Inc.