

Esclarecimentos sobre a possibilidade de contaminação do Thyrogen

American Thyroid Association

Dedicated to Scientific Inquiry, Clinical Excellence, Public Service, Education, and Collaboration



AMERICAN
THYROID
ASSOCIATION
FOUNDED 1923

FDA notification of Potential Contamination of Products Manufactured by Genzyme Corporation

The U.S. Food and Drug Administration is warning healthcare professionals about the potential for foreign particle contamination of several products manufactured by Genzyme Corporation that are used to treat rare, serious, and life-threatening diseases. The foreign particles, believed to be found in less than 1% of products based on product lots assessed to date, include stainless steel fragments, non-latex rubber from the vial stopper, and fiber-like material from the manufacturing process and could potentially cause serious adverse events in patients. This problem affects all lots of the below listed products which have the prefix "A" (e.g., Lot A12345). The affected products are manufactured by Genzyme Corporation at their Allston Landing, MA, facility.

The affected products include:

- Cerezyme (imiglucerase) for Gaucher disease
- Fabrazyme (agalsidase beta) for Fabry disease
- Myozyme/Lumizyme (alglucosidase alpha) for Pompe disease
- Aldurazyme (laronidase) for mucopolysaccharidosis I
- Thyrogen (thyrotropin alpha) used as an adjunctive diagnostic tool and treatment for thyroid cancer

At this time, no adverse event reports related to potential foreign particle contamination have been received by FDA. However, healthcare professionals should be alert for the development of adverse events.

For additional information, including considerations for healthcare professionals, please visit FDA's Web site at <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHealthcareProfessionals/ucm190400.htm>.

To report any unexpected adverse or serious events associated with the use of these products, please contact the FDA MedWatch program and complete a form online at <http://www.fda.gov/medwatch/report/hcp.htm> or report by fax to 1-800-FDA-0178, by mail using the postage-paid address form provided online, or by telephone to 1-800-FDA-1088.

Genzyme Corporation sends a letter to all health care practitioners:

A letter from Genzyme Corporation to all health care practitioners is available for download:

[Foreign Particles: ThyrogenR \(thyrotropin alfa for injection\) Letter from Genzyme](#) (PDF File, 144 KB)

For Further Information Contact:

The American Thyroid Association
6066 Leesburg Pike, Suite 550
Falls Church, VA 22041
Phone: (703) 998-8890
Fax: (703) 998-8893
email: thyroid@thyroid.org