

Dear stakeholders of the LSDP

The LSDP has been informed that Genzyme has detected foreign particles in some products filled at the Allston Landing facility in the course of routine quality control processes. These products include:

- Cerezyme (imiglucerase) for Gaucher disease
- Fabrazyme (agalsidase beta) for Fabry disease
- Aldurazyme (laronidase) for Mucopolysaccharidosis Type I

Further information is available

from: <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm190480.htm>

You may also be interested in information sent by Genzyme Corporation to Health Care associates in America. The letter is available from the FDA website at:

<http://www.fda.gov/downloads/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/UCM190590.pdf>

The LSDP understand that Genzyme Australia is in the process of sending out information to Health Care associates in Australia.

The following advice has been provided by our colleagues at the Therapeutic Goods Administration in regards to the implications for supply in Australia:

1. Healthcare professionals and patients be aware of the potential for foreign particle contamination that has been reported with Aldurazyme, Cerezyme, Fabrazyme and Myozyme manufactured overseas.
2. In Australia, Myozyme is manufactured at another site, but the following precautions are still recommended.
3. Aldurazyme has not been manufactured at the affected site since September 2008, however the risk for Aldurazyme currently in supply is unknown at this stage.
4. The particle contamination relates to metal fragments, non-latex rubber and fibres from the manufacturing process which could cause adverse events such as local pain, swelling and inflammation but could also be more serious such as damage to blood vessels or embolic events, anaphylactic reactions, allergic and immune-mediated reactions. It is also possible that the foreign particles could affect how well these products work.
5. Visually inspect the powder in the vial for the presence of particles before reconstitution.
6. Visually inspect the reconstituted powder in solution and the Aldurazyme solution for the presence of particles.
7. Do not administer any product which contains foreign matter or particles. These products should be returned to Genzyme, as well as the LSDP being notified.
8. For Cerezyme, Aldurazyme, Myozyme and Fabrazyme, use an in-line low protein-binding 0.2 or 0.22 micrometer filter. This is recommended in the product information for Cerezyme, Aldurazyme and Myozyme, and is intended to be updated shortly in the Fabrazyme product information to include such use and would be consistent with the Fabrazyme product information in the USA. However it is not clear if using an in-line filter will remove all foreign particles or whether foreign particles might affect the integrity of the in-line filter.
9. Observe patients for local or systemic infusion reactions after administration and to report any adverse events to the Office of Medicines Safety Monitoring at the TGA. No adverse events have been reported to the TGA related to this contamination.

10. A Dear Healthcare professional letter will be distributed shortly by Genzyme to all prescribers and pharmacists discussing the situation and reinforcing the need for visual inspection and use of in-line filters.

11. Doctors should discuss the situation with their patients and weigh up the risks and benefits of treatment.

12. At this stage, the TGA is not recommending a recall.

The LSDP would appreciate it if you could take the time to read through this information and also forward it to all individuals who are involved in the administration of treatment of Cerezyme, Fabrazyme and Aldurazyme.

Kind regards,

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