genzyme

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To whom it may concern:

All Fabrazyme lots meet approved quality standards. As per product labeling a visual inspection of the vials before and after reconstitution should be performed and the vials should not be used in case foreign particles are found or discoloration is present.

If foreign particles are found, the product should not be used and Genzyme Medical Information should be contacted; vials will be replaced.

Infusion sites should closely follow the preparation instruction in the package leaflet which includes visual inspection for foreign particles and discoloration as well as in line filtration.

A review of the global safety database for Fabrazyme (from January 2007 through November 05, 2009) has not revealed any safety concerns to suggest that patients treated with Fabrazyme have experienced events related to foreign particles.

The safety profile of Fabrazyme remains unchanged, with the above mentioned procedures in place the risk to patient health is remote.

Wytske Kingma, MD 17 nov 2009

Senior Vice President
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