



European Medicines Agency
Press office

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PRESS RELEASE

Supply shortage of Fabrazyme – updated treatment recommendations required for adult male patients

The European Medicines Agency has been informed by Genzyme, the marketing authorisation holder of Fabrazyme (agalsidase beta), that the supply shortage of the medicine is more severe than previously expected. The Agency's Committee for Medicinal Products for Human Use (CHMP) has therefore agreed to new temporary treatment recommendations, saying that not only female but also male patients should receive a reduced dose of Fabrazyme. These recommendations revise the recommendations proposed by the company in June 2009.

The updated recommendations during the supply shortage are as follows:

- Children and adolescents (<18 years) should receive Fabrazyme according to the recommended dose and frequency.
- Adult male patients and adult female patients already treated/stabilised may receive Fabrazyme with an adjusted dose of 0.3 mg/kg as maintenance dose every two weeks.
- Patients with adjusted dose regimens should be under close clinical surveillance. A full medical examination, including all relevant clinical parameters, should be performed every two months. It is of the utmost importance to monitor the plasma GL-3 or urinary GL-3 levels, as for the moment the GL-3 level is the most sensitive parameter. Patients who demonstrate a deterioration of disease should reinstitute the original treatment with Fabrazyme.

These are temporary recommendations and do not change the currently approved Product Information for Fabrazyme. It is expected that these changes will need to continue until the end of the year.

Fabrazyme is used in the treatment of patients with Fabry disease, a rare, inherited enzyme-deficiency disorder in which patients do not have enough of an enzyme called alpha-galactosidase A. The deficiency in this enzyme causes certain fat molecules to accumulate in the body's tissues, particularly the heart, kidneys, eyes and nerve tissue.

The supply shortage is caused by the shutting down of Genzyme's production site for Cerezyme and Fabrazyme in Allston Landing, in the United States of America in June 2009, because viral contamination (calicivirus of the type Vesivirus 2117) required sanitisation of the bioreactors. Therefore, the CHMP issued temporary changes to the way Cerezyme and Fabrazyme are prescribed and used in June 2009 to ensure that patients could continue to have access to these medicines while Genzyme was solving the manufacturing issues.

In August 2009, the Agency had to update the temporary changes for Cerezyme following notification by the company that the existing stocks for this medicine were lower than previously communicated.

Genzyme has now informed the Agency that inventories of Fabrazyme will also be lower than anticipated because of low yields of the enzyme after the manufacturing process was restarted.

Notes:

1. More information is available in a [question-and-answer document](#).
2. More information about the temporary recommendations from June 2009 is available [here](#).
3. More information about the updated temporary recommendations for Cerezyme from August 2009 is available [here](#).
4. More information on Cerezyme, including the currently approved Product Information, is available in the European Public Assessment Report:
<http://www.emea.europa.eu/humandocs/Humans/EPAR/cerezyme/cerezyme.htm>.
More information on Fabrazyme, including the currently approved Product Information, is available in the European Public Assessment Report:
<http://www.emea.europa.eu/humandocs/Humans/EPAR/fabrazyme/fabrazyme.htm>
5. This press release, together with other information on the work of the European Medicines Agency, can be found on the Agency website: www.emea.europa.eu

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