genzyme

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Direct Healthcare Professional Communication on the supply of Cerezyme® (imiglucerase) and Fabrazyme® (agalsidase beta) temporary treatment recommendations

Dear Healthcare Professional,

Genzyme would like to inform you that the production of Cerezyme and Fabrazyme has been temporarily suspended. As a result there will be a shortage of both medicinal products, which are used to treat patients with Gaucher disease and Fabry disease, respectively.

This shortage is to be resolved by the end of 2009 for both products. In the meantime, there is a risk of delays in fulfilling orders and of potential interruptions to therapy.

Following discussions with the European Medicines Agency (EMEA), Genzyme is providing temporary recommendations to ensure that patients with active disease progression continue to receive Cerezyme and Fabrazyme until inventory levels have returned to normal.

Cerezyme

The most frequently used treatment schedule for Cerezyme is one infusion every two weeks. During the shortage, treatment recommendations as agreed with the EMEA are as follows:

- Infants, children and adolescents should receive Cerezyme at the approved dose and infusion frequency, because these 'early-onset patients' have the most rapid disease progression and are at risk of serious long-term problems.
- Adult patients with active disease progression (e.g., pulmonary hypertension, active skeletal disease, severe thrombocytopenia or severe anaemia) should receive Cerezyme at the approved dose and infusion frequency.
- Adult patients without clinical evidence of active disease progression should receive Cerezyme at a reduced dose (e.g. 50% dose once every two weeks) or at a reduced infusion frequency (e.g. once a month at their current dose). No patient should be treated at a dose lower than 15 Units/kg every 2 weeks. These patients should be monitored for changes in haemoglobin, platelets and chitotriosidase levels, as appropriate, at baseline and bimonthly thereafter.

Fabrazyme

The most frequently used treatment schedule for Fabrazyme is one infusion every two weeks. During the shortage, treatment recommendations as agreed with the EMEA are as follows:

- Children and adolescents (<18 years), and adult males should receive Fabrazyme according to the recommended dose and frequency.
- Adult female patients, without evidence of clinically significant major organ dysfunction or damage may receive Fabrazyme with an adjusted dose of between 0.3-0.5 mg/kg every two weeks. These patients should be monitored for changes in urinary GL-3 levels at baseline and bimonthly thereafter.

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Adverse events for both Cerezyme and Fabrazyme should be reported as usual and physicians are reminded to document batch numbers in the patient record.

These are temporary recommendations and do not change the currently approved Product Information for both Cerezyme and Fabrazyme. The recommendations only apply until the supply problems have been resolved.

Should you require any further information, please contact Genzyme Medical Information via e-mail on ukmedinfo@genzyme.com or telephone + 44 (0)1865 405283

Yours sincerely,

Carlo Incerti, MD.
Head of R&D Europe