

Genzyme Logo

To whom this may concern

Naarden, [date] January 2009

Subject: Supply of Myozyme[®] (alglucosidase alfa) and temporary treatment recommendations

Dear Healthcare Professional,

Genzyme has informed the European Medicines Agency (EMA) that inventory levels of Myozyme, which is used to treat patients with Pompe disease, will be so tight in the first few months of 2009 that there is a risk of a delay in fulfilling orders and of potential interruptions in therapy.

As a result of discussions with the EMA, Genzyme has been asked to provide temporary recommendations on the management of patients with Pompe disease for physicians who prescribe Myozyme. These recommendations aim to ensure that infants, children and adolescents continue to receive Myozyme until inventory levels have returned to normal.

The EMA's Committee for Medicinal Products for Human Use (CHMP) has provided the following advice to help manage interruptions in treatment:

The approved treatment schedule for Myozyme is one infusion every two weeks. Because infants, children and adolescents ('early-onset patients') have the most rapid disease progression and are at risk of serious long-term developmental problems, it is recommended that:

- Infants, children and adolescents continue Myozyme treatment without any interruption. New treatments should be initiated when necessary without restriction in this age group.
- In adults, no new treatments with Myozyme should be initiated. Prescribers should consider temporary treatment interruption in adults already being treated until the supply problems are resolved, except in patients in whom interruption may have life-threatening consequences.

Should you require any further information, please contact Genzyme [countryname] via e-mail [insert e-mail address] or telephone [insert country phone number].

Yours sincerely,

Carlo Incerti, MD.
Head of R&D Europe