



19 July 2010

RE: Update on the Supply of Fabrazyme® (agalsidase beta-rch)

Dear Fabry Community,

Since the Fabrazyme supply shortages which started in July 2009, Genzyme has most recently had sufficient Fabrazyme to supply the Australian Government Life Saving Drugs Program (LSDP) at 30 per cent of normal demand. Genzyme would like to inform you that the supply of Fabrazyme (*agalsidase beta-rch*) for the period July through September 2010 will be lower again. Unfortunately, there continues to be insufficient Fabrazyme to fully address the medical needs of the patients currently receiving Fabrazyme in Australia today. It is unclear as to when supplies will increase, or the availability of Fabrazyme supply from October 2010.

As a result of the continued shortage, it is likely that some patients' doses may need to be further reduced. The Life Saving Drugs Program (LSDP) and the Fabry Disease Advisory Committee (FDAC) have advised that the following dose strategy will continue to apply:

1. Due to limitations in supply, newly identified Fabry patients are unable to be treated with Fabrazyme. If eligible through the LSDP, patients will only be approved for treatment with the alternate approved treatment (Replagal®, agalsidase alfa).
2. Doctors may apply to the LSDP to transfer their patient to Replagal at any time (email: lsdp@health.gov.au).
3. Doses are recommended to the Department by the FDAC with regard to objective measures of the patient's condition and any deterioration observed during the supply shortage period. Of patients who have elected to continue treatment with Fabrazyme, most will receive a rationed dose of Fabrazyme of approximately 0.3mg/kg/fortnight. Individual doses of Fabrazyme may be lower or higher depending on limitations in the product form and vial size availability.
4. In situations where the continuation of treatment with Fabrazyme is deemed medically necessary, it is important to note that an increase in clinical manifestations has been observed on lowered dose.
5. All patients, especially those with adjusted dose regimens should be under close clinical surveillance. A medical examination, including all relevant clinical parameters, should be performed at least every three months. It is of the utmost importance that clinical parameters be monitored over the course of this period to ensure appropriate tracking of response to therapy.
6. Clinicians are required to provide the LSDP with regular updates on patient conditions, to enable appropriate review and monitoring of deterioration (if any), and for dosing to be adjusted accordingly.



It is important that any safety concerns or potential adverse events associated with the use of these products be discussed with the treating physician, who will report these to the Therapeutic Goods Administration, Genzyme Australasia and the LSDP at the following:

Medicines Safety Monitoring
Reply Paid 100
Woden ACT 2606
1800 044 114
adr.reports@tga.gov.au

**Genzyme
Pharmacovigilance**
1800 359 131 (02) 9978 3900
PV_ANZ@genzyme.com

LSDP
PO Box 9848
Canberra ACT 2601
(02) 6289 2314
lsdp@health.gov.au

This information gives our best estimate of Fabrazyme supply at the current time. Since we continue to work with extremely limited inventory, even minor changes to our current manufacturing plan can impact our ability to supply Fabrazyme. Genzyme will continue to provide you with updates on the production and supply of Fabrazyme. We appreciate the Fabry community's ongoing patience as we work to resume more regular supply of Fabrazyme.

If you or a family member has any concerns about your condition, please contact your Fabry treatment centre.

For more information, please contact the LSDP at (02) 6289 2314 or lsdp@health.gov.au.

Yours sincerely,

Katy Williams Day
Director, Regulatory Affairs, Quality and Compliance