EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

28 October 2014
EMA/390682/2016

Update of 7 June 2016: the shortage affecting Fabrazyme has been resolved and the below information and recommendations which were issued during the shortage no longer apply.

Fabrazyme (agalsidase beta) **solution for infusion**	
Indication	Fabrazyme is used to treat patients who have Fabry disease.
Reason for shortage	The supply shortage of Fabrazyme began in June 2009 and was caused by a series of manufacturing problems at one of its manufacturing sites. Information issued previously by the EMA on the supply situation for Fabrazyme can be found here.
Member States affected[1]	All European Union (EU) Member States.
Information to healthcare professionals	• Product supply remains vulnerable to disruption. • Based on current stock levels, patients can receive the full dose of Fabrazyme recommended in the summary of product characteristics. • Healthcare professionals who wish to start new patients should contact the company prior to starting treatment. New patients can be started as long as existing stocks are sufficient. • Additional advice may be available from the national competent authority.
Information to patients	• Product supply remains vulnerable to disruption. • For patients who are currently being treated with Fabrazyme, the treating doctor will be able to prescribe the full dose. • New patients can start receiving Fabrazyme as long as existing stocks are sufficient. • Patients who have any questions should speak to their doctor or pharmacist. • Additional advice may be available from the national competent authority.

[1] This information may change. For accurate information about the status of a medicine shortage in a particular Member State the national competent authority should be contacted.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

	• Patients may also contact Eurordis, an organisation representing people with rare diseases in Europe, or Fabry International Network (FIN).