

VANCOUVER HOSPITAL & HEALTH SCIENCES CENTRE
PHARMACY SERVICES
DRUG DATA SHEET

DRUG NAME

Recombinant human α -galactosidase

ALTERNATE NAMES

Fabrazyme™
r-h α -GAL
agalsidase beta

MANUFACTURER

Genzyme

STRENGTH

35 mg vials

DOSAGE FORM

injection

INDICATIONS

- enzyme replacement therapy for the treatment of Fabry Disease, an enzyme deficiency disorder

DOSAGE AND ADMINISTRATION

- 0.9 – 1.1mg/kg IV infused over 4-6hours every 2 weeks x 52 weeks

KNOWN SIDE EFFECTS*

- most common adverse event is transient mild to moderate hypertension
- allergic reactions, pain, headache, fever, abdominal pain
- infusion-related reactions are common and include rigors (fever and chills), headache, flushing, elevated blood pressure or skeletal pain

SPECIAL PRECAUTIONS

- keep drug refrigerated
- reconstitute drug with 7.2 mL of sterile water for injections (preservative free) to provide 5mg/mL
- reconstituted drug is stable for 24 hours at room temperature or in refrigerator
- dose is further diluted in 500mL of NS. The diluted solution is stable for 24 hours when refrigerated
- infuse dose over 4-6 hours as per protocol via dedicated line
- not compatible with other drugs
- patients who develop hypersensitivity reactions can continue α -galactosidase infusions with appropriate pre-treatment, a reduction of the infusion rate, or a temporary reduction in dosage
- observe patients for 1 hours post-infusion
- monitor vital signs (BP, HR, RR) prior to and post infusion

***REPORT ANY ADVERSE DRUG REACTIONS TO THE PHARMACY**

galactosidase
rev Feb/02