

Consumer Medicine Information

LOGO

Fabrazyme[®]

(agalsidase beta - rch)

Powder for concentrate for solution for infusion

This leaflet does not have the complete information available about this medicine. When you have read this leaflet, if you want more information, please ask your pharmacist or doctor.

IDENTIFICATION

Fabrazyme[®] is a white to off-white powder which is reconstituted with sterile water and diluted with saline for intravenous infusion.

Each vial of Fabrazyme[®] contains agalsidase beta – rch as the active ingredient. This is a form of the human enzyme, alpha-galactosidase produced by recombinant DNA technology.

Fabrazyme[®] also contains the following inactive ingredients (excipients).

- Mannitol
- Monobasic sodium phosphate (monohydrate)
- Dibasic sodium phosphate

Fabrazyme[®] contain no preservatives.

Fabrazyme[®] is available in a 5 or 20 mL glass vial containing an extractable amount of 5mg (AUSTR 94000) or 35 mg (AUSTR 82755) of agalsidase beta-rch per vial respectively.

WHAT IS FABRAZYME[®] USED FOR?

Fabrazyme[®] is used as enzyme replacement therapy in Fabry disease, where the level of alpha-galactosidase activity is absent or lower than normal.

HOW DOES FABRAZYME[®] WORK?

Patients with Fabry disease do not produce enough of their own enzyme – alpha-galactosidase. This means that a fat substance, called globotriaosylceramide (GL-3), is not removed from the cells of your body and starts to accumulate in the walls of the blood vessels of your organs. Fabrazyme[®] removes GL-3 from the walls of blood vessels in the kidney, heart and skin.

ADVICE BEFORE USING FABRAZYME[®]

Do not use Fabrazyme[®] if you have experienced a severe allergic reaction to any of the ingredients of the product.

In clinical trials, the majority of patients developed antibodies against the active ingredient and most continued treatment. If you develop antibodies to the active ingredient you have a higher risk of allergic side effects (See Undesirable Effects). If you experience an allergic side effect following the administration of Fabrazyme[®], you should immediately contact your doctor. Before the administration of Fabrazyme[®] your doctor might administer paracetamol and antihistamines and/or corticosteroids in order to minimise the re-occurrence of the effects.

It is not known whether Fabrazyme[®] can cause foetal harm when administered to pregnant or nursing women, or whether Fabrazyme[®] affects reproductive capacity. Ask

your doctor or pharmacist for advice before taking this medicine.

Fabrazyme[®] should not be administered as a mixture with other medicinal products in the same infusion. Please inform your doctor or pharmacist if you are taking, or have recently taken, any other medicine, even those not prescribed.

HOW TO USE FABRAZYME[®] PROPERLY

The Fabrazyme[®] powder in the vial, for solution and infusion, has first to be reconstituted with sterile water for injection, diluted in 0.9% sodium chloride intravenous solution, and then administered by intravenous infusion.

The total time between reconstitution and completion of the infusion should not exceed 24 hours. The total infusion time should not be less than 2 hours in order to minimise the risk of allergic side effects.

Do not take a double dose to make up for forgotten individual doses.

OTHER INFORMATION

A doctor's prescription is required for Fabrazyme[®] and it would normally be made available to you via the doctor, through a hospital pharmacy.

UNDESIRABLE EFFECTS

Like all medicines, Fabrazyme[®] can have side effects.

- Very common (> 10%): chills, temperature changed sensation, chest pain, high blood pressure, abdominal pain, muscle pain, fever, headache, shaking, nausea, runny nose, pain at the extremities, red face, itching, vomiting, shortness of breath and sleepiness.
- Common (5 – 10%): pain, fatigue, discomfort, weakness, leg pain, dizziness, tingling (pins and needles), increased or decreased heart beat, difficulty in breathing, throat tightness and abnormal tearing.

Side effects were mostly mild to moderate in severity.

Approximately half of the patients experienced related side effects on the day of infusion. These reactions consisted most often of fever/chills. Additional symptoms included allergic like reactions with mild to moderate shortness of breath, throat tightness, chest tightness, red face, itching, hives, rhinitis, difficulty in breathing, rapid breathing and/or wheezing; heart and blood vessel symptoms including moderate high blood pressure, increased heart rate, palpitations; stomach and bowel symptoms including abdominal pain, nausea, vomiting; infusion-related pain including pain at extremities and muscle pain and headache.

These allergic like symptoms were managed by a reduction in the rate of infusion together with the administration of paracetamol (or equivalent). Four patients experienced symptoms similar to those mentioned above however in a more severe form. Blood tests revealed that these 4 patients had an immune reaction to Fabrazyme[®] that resulted in suspension of future infusions.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist. He or she may

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request you to have your blood tested prior to subsequent infusions.

STORAGE CONDITIONS

Keep Fabrazyme[®] vials out of reach of children.

Unopened vials should be stored at 2°C to 8°C. (Refrigerate. Do not freeze).

DO NOT USE Fabrazyme[®] after the expiration date on the carton.

To reduce microbiological hazard, use as soon as practicable after reconstitution/dilution.

If necessary, Fabrazyme[®] diluted for infusion in sterile 0.9% Sodium Chloride for Injection, is stable for up to 24 hours when stored at 2°C to 8°C.

DATE OF THIS TEXT

02 April 2004.

SPONSOR

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