FABRAZYME® *[fab-ra-ZIME]*

Agalsidase beta-rch *[ag-al-SI-daze al-fa R.C.H]* 5.5 & 35 mg/mL, Powder for Concentrate for Solution for Infusion

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about FABRAZYME.

It does not contain all the available information.

It does not take the place of talking to your treating physician or a trained health care professional.

All medicines have risks and benefits. Your treating physician has weighed the risks of you or your child having FABRAZYME against the benefits they expect it will have.

If you have any concerns about this medicine, ask your treating physician or nurse.

Keep this leaflet.
You may need to read it again.

What FABRAZYME is used for

FABRAZYME is used as enzyme replacement therapy in Fabry's Disease, a disease in which the level of an enzyme called α-galactosidase is lower than normal.

How it works

Patients with Fabry's Disease do not produce enough of their own enzyme, α-galactosidase. The reduced α-galactosidase activity in patients results in the accumulation of substances called glycosphingolipids, predominantly globotriaosylceramide (GL-3) in a number of cell types and tissues.

FABRAZYME is an enzyme replacement therapy that is intended to restore a level of enzyme activity sufficient to remove the accumulated substances and to prevent further accumulation.

Before you are given FABRAZYME

When you or your child must not be given it

Do not take FABRAZYME if you or your child have a known, severe, life-threatening allergic reaction to:

- FABRAZYME
- any of the ingredients listed at the end of this leaflet

Symptoms of an allergic reaction may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- skin rash, itching or hives

If you are not sure whether you or your child should have FABRAZYME, talk to your treating physician or nurse.

Before you or your child are given it

Tell your treating physician if your child is under 8 years of age and has been prescribed FABRAZYME.

Safety in children below the age of 8 years has not been studied. If your child has been prescribed FABRAZYME, you may wish to discuss this with your child's treating physician.

Tell your treating physician if you or your child have reacted to previous treatments with FABRAZYME.

Tell your treating physician if you or your child have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes

Tell your treating physician if you are pregnant or intend to become pregnant.

There is no information available regarding the use of FABRAZYME in pregnant women. Your treating physician will discuss the possible risks and benefits of having FABRAZYME during pregnancy.

Tell your treating physician if you are breast-feeding.

FABRAZYME is not recommended for use when breast-feeding as it is not known whether FABRAZYME passes into breast milk. If there is a need to consider using FABRAZYME while you are breast-feeding, your treating physician will discuss with you the benefits and risks of using it.

Taking other medicines

Tell your treating physician or nurse if you or your child are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

No studies have been carried out between FABRAZYME and other medicines. However, some medicines and FABRAZYME may interfere with each other.

Tell your treating physician or nurse if you or your child are using other medicines as these medicines may be affected by FABRAZYME, or may affect how well it works. You or your child may need different amounts of these medicines or different medicines may need to be taken. Your treating physician or nurse will advise you and decide whether or not to give you or your child the medicine.

How FABRAZYME is given

The recommended dosage for FABRAZYME is 1 mg/kg of body weight once every two weeks. FABRAZYME will be given to you or your child directly into the vein (intravenously) by a trained health care professional in a hospital or a clinic.

The treating physician or nurse will decide on the dose that is most suitable. They will also tell you how long it will take to give the medicine. It may take several hours.

If you are given too much (overdose)

There have been no reported overdoses of FABRAZYME.

Your treating physician is trained to work out the correct dose and to contact the Australian Poisons Information Centre (telephone 13 11 26), or the New Zealand National Poisons Centre (telephone 0800 POISON or 0800 764 766) in case of an overdose.

Things you or your child must do

Keep appointments with your treating physician or clinic.

It is important to have the FABRAZYME infusion at the appropriate times to make sure the medicine has the best chance of providing treatment for the condition.

After having FABRAZYME

Have any tests when your treating physician says to.

Your treating physician may wish to test you or your child's body's response to FABRAZYME to make sure that it is working.

Things to be careful of

Be careful driving or operating machinery until you know how FABRAZYME affects you.

The effect of FABRAZYME on your ability to drive a car or operate machinery has not been studied. Make sure that you know how you react to FABRAZYME before you drive a car or operate machinery or do anything else that may be dangerous if you are dizzy, lightheaded, tired or drowsy.

Side effects

Tell your treating physician or nurse as soon as possible if you or your child do not feel well after having FABRAZYME.

FABRAZYME may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not.

Ask your treating physician or nurse to answer any questions you may have.

Tell your treating physician or pharmacist if you notice any of the following and they worry you:

- shortness of breath, wheezing or coughing, difficulty breathing
- local reaction around the injection site such as redness, itchiness, tenderness, pain or discomfort, warmth, burning or stinging, swelling or the formation of hard lumps or scars
- itchy rash, hives, itching or rash
- flushing or redness of the skin
- pale skin
- headaches
- chest pain
- soreness, aching muscles, muscle tenderness, weakness (not caused by exercise), shaking or pins and needles
- stomach-ache
- increase or decrease in your heart beat
- swelling of the face, lips, mouth, tongue or throat
- difficulty swallowing
- nausea, vomiting
- sleepiness
- dizziness and lightheadedness
- runny nose

Other side effects not listed above may occur in some patients. Tell your treating physician if you notice anything making you feel unwell when you are taking, or soon after you have finished taking FABRAZYME.

Storing FABRAZYME

FABRAZYME will be stored in the hospital or clinic pharmacy.

FABRAZYME will be used immediately after it has been prepared for infusion.

Product Description

What it looks like

FABRAZYME is a white to off-white powder before it is prepared for infusion and a clear, colourless solution after it has been prepared for infusion.

Ingredients

Active ingredient: agalsidase beta

Other ingredients: mannitol, sodium phosphate - monobasic monohydrate, dibasic sodium phosphate heptahydrate.

Supplied by

Genzyme Australasia Pty. Ltd.
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