FABRAZYME®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I being given FABRAZYME?

FABRAZYME contains the active ingredient agalsidase beta-rch. FABRAZYME is used as enzyme replacement therapy in Fabry Disease. For more information, see Section 1. Why am I being given FABRAZYME? in the full CMI.

2. What should I know before I am given FABRAZYME?

You or your child should not be given FABRAZYME if you or your child have ever had an allergic reaction to agalsidase beta or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you or your child have any other medical conditions, take any other medicines, or if you are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I am given FABRAZYME? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with FABRAZYME and affect how it works. Check with your doctor if you are not sure about what medicines, vitamins or supplements you or your child are taking and if these affect FABRAZYME.

For more information, see Section 3. What if I am taking other medicines? in the full CMI.

4. How is FABRAZYME given?

- The recommended dosage for FABRAZYME is 1 mg/kg of body weight given 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.
- Your doctor may advise that you can be treated at home provided you meet certain criteria. Please contact your doctor if you would like to be treated at home.

More information can be found in Section 4. How is FABRAZYME given? in the full CMI.

5. What should I know while being given FABRAZYME?

Things you should do	• Remind any doctor, dentist or pharmacist you or your child visit that you or your child are being given FABRAZYME. • Attend appointments with your treating doctor or clinic. • Have any tests when your treating doctor says to.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how FABRAZYME affects you. • Children should be careful when undertaking activities requiring attention such as riding bicycles or climbing. • FABRAZYME may cause dizziness, lightheadedness, tiredness and sleepiness in some people.
Looking after your medicine	• FABRAZYME will be stored in the hospital or clinic pharmacy. • FABRAZYME will be used immediately after it has been prepared for infusion.

For more information, see Section 5. What should I know while being given FABRAZYME? in the full CMI.

6. Are there any side effects?

Common and less serious side effects include headaches, dizziness and lightheadedness, sleepiness, 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, runny nose, flushing or redness of the skin, pale skin, soreness, aching muscles, muscle tenderness, weakness (not caused by exercise), shaking or pins and needles, nausea, vomiting, and stomach-ache.
Serious side effects include signs of allergic reaction (shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, skin rash, itching or hives), difficulty swallowing, changes in your heartbeat (increase or decrease), and chest pain.
For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

FABRAZYME® (fab-ra-ZIME)

Active ingredient(s): *agalsidase beta-rch* (ag-al-SI-daze bee-ta R.C.H)

Consumer Medicine Information (CMI)

This leaflet provides important information about using FABRAZYME. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using FABRAZYME.**

Where to find information in this leaflet:

1. Why am I being given FABRAZYME?
2. What should I know before I am given FABRAZYME?
3. What if I am taking other medicines?
4. How is FABRAZYME given?
5. What should I know while being given FABRAZYME?
6. Are there any side effects?
7. Product details

1. Why am I using FABRAZYME?

FABRAZYME contains the active ingredient agalsidase beta-rch. FABRAZYME is a recombinant human α-galactosidase. Patients with Fabry Disease do not produce enough of their own α-galactosidase enzyme. Reduced levels of α-galactosidase enzyme results in the accumulation of substances called glycosphingolipids in a number of cell types and tissues.

FABRAZYME is used as enzyme replacement therapy in Fabry Disease. It is intended to restore a level of enzyme activity sufficient to remove the accumulated substances and to prevent further accumulation.

2. What should I know before I am given FABRAZYME?

Warnings

You/your child should not be given FABRAZYME if:

- you are allergic to agalsidase-beta, agalsidase, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you/your child:

- have any other medical conditions
- take any medicines for any other condition.

During treatment, you or your child may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Your treating doctor will discuss the possible risks and benefits of receiving FABRAZYME during pregnancy.

FABRAZYME should only be used during pregnancy if clearly needed.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Caution should be exercised when FABRAZYME is used while breast-feeding as many drugs pass into breast milk. If there is a need to consider using FABRAZYME while you are breast-feeding, your treating doctor will discuss with you the benefits and risks of using it.

Children under 8 years of age

Tell your doctor 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 doctor.

3. What if I am taking other medicines?

Tell your doctor or nurse if you or your child are taking any other medicines, including any medicines, vitamins or supplements 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 doctor or nurse if you or your child are taking 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 doctor or nurse will advise you and decide whether or not to give you or your child the medicine.

Check with your doctor if you are not sure about what medicines, vitamins or supplements you or your child are taking and if these affect FABRAZYME.

4. How is FABRAZYME given?

How much is given

- The recommended dosage for FABRAZYME is 1 mg/kg of body weight given once every two weeks.
- The treating doctor 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.

How Fabrazyme is given

- 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.
- FABRAZYME is only used under the supervision of a doctor who is knowledgeable in the treatment of

Fabry disease. Your doctor may advise that you can be treated at home provided you meet certain criteria. Please contact your doctor if you would like to be treated at home.
- A Home Infusion Guide for Patients/Carers is available to provide home infusion information related to FABRAZYME. Please ask your doctor for more information.

If you are given too much FABRAZYME

Your treating doctor is trained to work out the correct dose and to phone the Poisons Information Centre (**by calling 13 11 26**), in case of an overdose. There have been no reported overdoses of FABRAZYME.

If you think that you or your child have been given too much FABRAZYME, you may need urgent medical attention.

5. What should I know while being given FABRAZYME?

Things you should do

Keep appointments with your treating doctor or clinic.

It is important for you or your child to receive FABRAZYME infusions at the appropriate times to make sure the medicine has the best chance of providing treatment for the condition.

Have any tests when your treating doctor says to.

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

Remind any doctor, dentist or pharmacist you or your child visit that you or your child are being treated with FABRAZYME.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how FABRAZYME affects you.

FABRAZYME may cause dizziness, lightheadedness, tiredness and sleepiness in some people.

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.

Children should be careful when undertaking activities requiring attention such as riding bicycles or climbing.

The effect of FABRAZYME on your ability to drive a car or operate machinery has not been studied.

Looking after your medicine

FABRAZYME will be stored in the hospital or clinic pharmacy.

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

6. Are there any side effects?

All medicines can have side effects. If you or your child do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor, nurse or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Alertness and sleep-related: • headaches • dizziness and lightheadedness • sleepiness. **Injection site-related:** • 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. **Sight, hearing, smell, taste or touch-related:** • runny nose. **Skin and muscle-related:** • flushing or redness of the skin • pale skin • soreness, aching muscles, muscle tenderness, weakness (not caused by exercise), shaking or pins and needles. **Stomach and gut-related:** • nausea, vomiting • stomach-ache.	**Speak to your doctor or nurse if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
Allergy-related: • itchy rash, hives, itching or rash • shortness of breath, wheezing or coughing, difficulty breathing • swelling of the face, lips, mouth, tongue or throat • difficulty swallowing. **Heart-related:** • increase or decrease in your heartbeat • chest pain.	**Tell your doctor or nurse straight away, if you notice any of these serious side effects.**

Tell your doctor or nurse if you notice anything else that may be making you or your child feel unwell while you or your child are being given FABRAZYME, or soon after having finished being given FABRAZYME.

Other side effects not listed here may occur in some people.

Reporting side effects

After you or your child have received medical advice for any side effects you or your child experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What FABRAZYME contains

Active ingredient (main ingredient)	agalsidase beta
Other ingredients (inactive ingredients)	• mannitol • monobasic sodium phosphate monohydrate • dibasic sodium phosphate heptahydrate

Do not take this medicine if you are allergic to any of these ingredients.

What FABRAZYME 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.

FABRAZYME 5 mg is supplied in clear 5 mL glass vials (Aust R 94000).

FABRAZYME 35 mg is supplied in clear 20 mL glass vials (Aust R 82755).

Each pack contains 1 vial.

Who distributes FABRAZYME

Distributed by:

sanofi-aventis australia pty ltd

International Tower 3, Level 23
300 Barangaroo Avenue
Sydney NSW 2000

Freecall: 1800 818 806

Email: medinfo.australia@sanofi.com

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