

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 using Kanuma?

Kanuma contains the active ingredient sebelipase alfa rce. Sebelipase alfa rce is similar to the naturally occurring enzyme lysosomal acid lipase (LAL), which the body uses to breakdown fats. Kanuma is used to treat patients of all ages with lysosomal acid lipase deficiency (LAL-D).

For more information, see Section [1. Why am I using Kanuma?](#) in the full CMI.

2. What should I know before I use Kanuma?

Do not use if you or your child has had a life-threatening allergic reaction to Kanuma, or to egg, or any of the ingredients listed at the end of the CMI.

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

For more information, see Section [2. What should I know before I use Kanuma?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Kanuma and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Kanuma?

- Your doctor or nurse will give Kanuma to you or your child by an infusion (drip) into a vein.

More instructions can be found in Section [4. How do I use Kanuma?](#) in the full CMI.

5. What should I know while using Kanuma?

| | |
|------------------------------------|---|
| Things you should do | <ul style="list-style-type: none">Ask your doctor if you have any questions about why this medicine has been prescribed for you or your child.Remind any doctor, dentist, nurse or pharmacist you visit that you or your child are using Kanuma.Keep appointments with your doctor or clinic. It is important to have you or your child's Kanuma infusion at the appointed time each time to make sure Kanuma has the best chance of providing effective treatment for the condition.This medicine may contain egg proteins. If you or your child has an egg allergy or a history of allergies to eggs, tell your doctor or nurse. You must not be given Kanuma. |
| Things you should not do | <ul style="list-style-type: none">Do not stop taking your medicine without checking with your doctor. |
| Driving or using machines | <ul style="list-style-type: none">Kanuma has not been shown to impair the ability to drive or operate machinery. However, if you experience dizziness, a reported side effect, then you should not drive or operate machinery until it has resolved. |
| Looking after your medicine | <ul style="list-style-type: none">Store under refrigeration (2°C to 8°C) and protected from light in the hospital or pharmacy. |

For more information, see Section [5. What should I know while using Kanuma?](#) in the full CMI.

6. Are there any side effects?

Kanuma contains a protein and proteins can cause allergic reactions in some people including serious, potentially life-threatening allergic reaction. If you or your child experiences a severe infusion reaction like this, seek immediate medical attention.

The development of blood proteins against Kanuma, also called anti-drug antibodies, may occur during the treatment. Talk to your doctor if you experience decreased efficacy with Kanuma.

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.

KANUMA[®] (ka-nu-ma)

Active ingredient(s): [sebelipase alfa,rce]

Consumer Medicine Information (CMI)

This leaflet provides important information about using Kanuma.

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 Kanuma.

Where to find information in this leaflet:

- [1. Why am I using Kanuma?](#)
- [2. What should I know before I use Kanuma?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Kanuma?](#)
- [5. What should I know while using Kanuma?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Kanuma?

Kanuma contains the active ingredient sebelipase alfa rce.

Sebelipase alfa rce is similar to the naturally occurring enzyme lysosomal acid lipase (LAL), which the body uses to breakdown fats.

Kanuma is an enzyme replacement therapy. This means that it replaces the missing or defective LAL enzyme in patients with LAL-D.

Kanuma is used to treat patients of all ages with lysosomal acid lipase deficiency (LAL-D).

Kanuma works by lowering the buildup of fat that causes medical complications, including impaired growth, digestive problems, liver damage, including liver failure and heart complications. It also improves blood levels of fats, including reducing elevated low-density lipoprotein cholesterol (LDL; also known as bad cholesterol) and triglycerides.

2. What should I know before I use Kanuma?

Warnings

Do not use Kanuma if you or your child has had a life-threatening allergic reaction:

- to sebelipase alfa rce,
- to any of the ingredients listed at the end of this leaflet, or
- to egg

that cannot be managed when you or your child receives Kanuma again.

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- Some 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,
- rash, itching or hives on the skin.

If you are not sure whether you or your child should be treated with Kanuma, talk to your doctor.

You or your child may experience side effects while being given Kanuma, or during the hours following the infusion. This is known as an infusion reaction. It can sometimes be severe and may include an allergic reaction (see above "Some symptoms of an allergic reaction may include"). If you or your child experiences a severe infusion reaction, seek immediate medical attention.

If you or your child has an infusion reaction you may be given additional medicines to treat or prevent future reactions. These medicines may include antihistamines, fever-reducing medicines or corticosteroids (a type of anti-inflammatory medicines).

If the infusion reaction is severe, your doctor may stop the infusion.

Check with your doctor if you:

- or your child has allergies to any other medicines, foods, preservatives, or dyes.

During treatment, you 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 doctor can discuss with you the risks and benefits involved. There is insufficient data from the use of Kanuma in pregnant women to determine if sebelipase alfa rce exposure during pregnancy poses any risk to the mother or fetus.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known whether Kanuma passes into breast milk. You should not breast feed while using Kanuma unless you have discussed it with your doctor.

Your doctor will discuss the benefits and risks of continuing treatment with Kanuma whilst breastfeeding.

3. What if I am taking other medicines?

Tell your doctor or pharmacist 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.

It is not known if Kanuma interferes with other medicines or other medicines affects Kanuma and how it works.

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

4. How do I use Kanuma?

Follow all directions given to you by your doctor, nurse or pharmacist carefully. They may differ from the information contained in this leaflet.

The dose you or your child receives is based on body weight.

Infants (less than 6 months of age)

For patients who have signs and symptoms of the disease when they are infants, the recommended starting dose is 1 mg per kg of body weight once weekly.

Children and adults

The recommended dose is 1 mg per kg body weight once every two weeks.

Dose adjustments may be considered based on how well your child responds to treatment.

Kanuma should be started at as young an age as possible and is intended for long-term use.

Your doctor or nurse will give Kanuma to you or your child by an infusion (drip) into a vein. Kanuma will be diluted before being administered.

Each infusion will take approximately 1 to 2 hours. You or your child will be monitored by your doctor or nurse after infusion.

If you forget to use Kanuma

If you forget or miss you or your child's appointment for a Kanuma infusion, contact your doctor immediately.

If you use too much Kanuma

As Kanuma is given to you or your child under the supervision of your doctor, it is unlikely that you will receive too much.

5. What should I know while using Kanuma?

Things you should do

- Tell any other doctors, dentists, and pharmacists who treat you that you or your child is taking this medicine.
- Keep appointments with your doctor or clinic. It is important to have your or your child's Kanuma infusion at the appointed time each time to make sure Kanuma has the best chance of providing effective treatment for the condition.

Call your doctor straight away if you:

If you or your child experiences a severe infusion reaction.

You or your child may experience a side effect while you or your child is being given Kanuma or during the hours following the infusion.

This is known as an infusion reaction which can sometimes be severe and may include an allergic reaction that could be life-threatening and require medical treatment.

Things you should not do

- Do not stop using this medicine suddenly.

Driving or using machines

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

It is not known if Kanuma impairs the ability to drive or operate machinery. However, if you experience dizziness, a reported side effect it could affect your ability to drive or operate machinery until it has resolved.

Looking after your medicine

Kanuma will be stored under refrigeration (2°C to 8°C, do not freeze) in the original packaging in order to protect from light in the hospital or pharmacy.

When to discard your medicine

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you 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 or pharmacist if you have any further questions about side effects.

Less serious side effects

| Less serious side effects | What to do |
|--|---|
| <p>Side effects reported in infants (1 to 6 months old) are:</p> <ul style="list-style-type: none"> • Eyelid swelling • Fast heartbeat • Diarrhoea • Vomiting • Rash, raised rash • Fever • Low red blood cell count • Running nose, cold, cough • Development of blood proteins against the drug • Catheter related infection • Reaction at the site of infusion <p>Side effects reported in children and adults are:</p> <ul style="list-style-type: none"> • Headache • Dizziness • Stomach-ache, diarrhoea, constipation, nausea • Tiredness • Fever • Cold, throat pain • Rash, raised rash • Stomach bloating | <p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> |

Serious side effects

| Serious side effects | What to do |
|---|---|
| <ul style="list-style-type: none"> • Severe allergic reaction (anaphylactic reaction), hypersensitivity (chills, eczema, laryngeal oedema, nausea, itching and hives, decreased oxygen in the blood, blood pressure increased, rapid breathing. • Allergy may also present as: Fast heartbeat, low blood pressure, shortness of breath, difficulty breathing, rapid breathing, chest discomfort, mild swelling of eyelids, red eyes, runny nose, flushing, hives, itching, diarrhoea, paleness, wheezing, low blood oxygen, skin redness, irritability. | <p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects</p> |

| Serious side effects | What to do |
|---|------------|
| <ul style="list-style-type: none"> In infants, allergic reaction may present as irritability, agitation, vomiting, hives, eczema, itching, paleness. | |

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

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

Reporting side effects

After you have received medical advice for any side effects you 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 Kanuma contains

| | |
|---|---|
| Active ingredient (main ingredient) | Sebelipase alfa rce |
| Other ingredients (inactive ingredients) | Sodium citrate Citric acid monohydrate Albumin Water for Injection |
| Potential allergens | Egg |

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

What Kanuma looks like

Kanuma is a clear to slightly opalescent, and colourless to slightly coloured solution contained in a glass vial

Pack size: 1 vial containing 10 mL of concentrate (AUST R 274498).

Who distributes Kanuma

Alexion Pharmaceuticals Australasia Pty Ltd
Suite 401, Level 4, Building A.
20 Rodborough Road
Frenchs Forest
NSW 2086
Medical enquiries: 1800 788 189

This leaflet was prepared in October 2021.