

KANUMA®

sebelipase alfa, rce

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about KANUMA®. It does not contain all the available information.

It does not take the place of talking to your doctor, nurse or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using KANUMA against the benefits they expect it will have for you.

If you have any concerns about this medicine, ask your doctor.

Keep this leaflet.

You may need to read it again.

What KANUMA is used for

KANUMA is a medicine containing the active substance; 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).

How it works

KANUMA is an enzyme replacement therapy. This means that it replaces the missing or defective LAL enzyme in patients with 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 LDL (bad cholesterol) and triglycerides.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

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

Before you use KANUMA

When you must not use KANUMA

Do not use KANUMA if you or your child has had:

- a life-threatening allergic reaction;
 - to sebelipase alfa rce, or
 - to egg, or
 - to any of the ingredients listed at the end of this leaflet

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

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.

Before you start to use KANUMA

You or your child may experience side effects while being given the medicine, 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 "symptoms of an allergic reaction"). 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.

Tell your doctor if you or your child has allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you are pregnant, or want to become pregnant.

Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you are breastfeeding.

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.

If you have not told your doctor about any of the above, tell them before you start using KANUMA.

Taking other medicines

Tell your doctor or pharmacist if you or your child is taking any other medicines or supplements, including any that you buy without prescription from your pharmacy, supermarket or health food shop.

Some medicines and KANUMA may interfere with each other. They may be affected by KANUMA or may affect how well it works. You may need different amounts of your medicines or may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking this medicine.

How to 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. The recommended dose is 1 mg per kg of body weight per fortnight (every 2 weeks). For children less than 6 months, the recommended starting dose is 1 mg per kg of body weight per week.

Dose adjustments may be considered based on how well you or 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. The medicine 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 miss a dose

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

If you use too much (overdose)

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

While you are using KANUMA

Things you must 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 the medicine has the best chance of providing effective treatment for the condition.

If you become pregnant while using KANUMA, tell your doctor immediately.

Your doctor will discuss the benefits and risks of continuing treatment with KANUMA during pregnancy.

If you intend to breastfeed whilst using KANUMA, consult your doctor.

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

Side Effects

Tell your doctor, nurse or pharmacist as soon as possible if you or your child does not feel well while you are being treated with KANUMA.

All medicines can have side effects. Sometimes they are serious; most of the time they are not. You may need medical attention if you get some of the side effects.

Tell your doctor or nurse if you notice any of the following and they worry you:

- diarrhoea or constipation
- vomiting, stomach pain, or feeling sick (nausea)
- low blood pressure (feeling dizzy or lightheaded) or high blood pressure
- fever, shiver, chills or high temperature
- runny or blocked nose, sneezing, facial pressure or pain
- tiredness, headache, being short of breath when exercising, dizziness and looking pale
- cough
- pinkish itchy swellings on the skin also called hives or nettle rash,
- red itchy rash, red swollen skin
- eyelid swelling
- sore or inflamed throat
- unusual weakness
- low muscle strength, unusual muscle slackness
- feeling anxious or nervous (sweating, trembling, fast heart beat)

The above list includes the more common side effects of KANUMA.

KANUMA contains a protein and proteins can cause allergic reactions in some people.

Tell your doctor immediately or go to Emergency at your nearest hospital if you notice any of the following.

Symptoms of such reactions 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
- fast heart rate
- chest pain or discomfort

The above lists include serious side effects that may require medical attention.

Other side effects not listed above may occur in some patients. Tell your doctor, nurse or pharmacist if you notice anything that is making you feel unwell.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

® = Registered Trademark

Storing KANUMA

KANUMA will be stored under refrigeration (2°C to 8°C) and protected from light in the hospital or pharmacy.

Product Description

What KANUMA looks like

KANUMA is a clear, colourless, solution contained in a glass vial.

Ingredients

Active ingredient

- sebelipase alfa, rce

Other ingredients

- sodium citrate
- citric acid monohydrate
- albumin
- Water for Injections

This product may contain traces of egg protein.

Manufacturer

Alexion Pharmaceuticals
Australasia Pty Ltd.
Suite 401, Level 4, Building A. 20
Rodborough Rd. Frenchs Forest.
NSW 2086.

Medical enquiries: 1800 788 189

Registration numbers;

AUST R 274498

This leaflet was prepared in May
2017