

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 Cerdelga?

Cerdelga contains the active ingredient eliglustat. Cerdelga is used for the long-term treatment of adult patients with Gaucher disease type 1.

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

2. What should I know before I use Cerdelga?

Do not use if you have ever had an allergic reaction to Cerdelga 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 Cerdelga?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Cerdelga 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 Cerdelga?

- If you are an intermediate metaboliser or extensive metaboliser: swallow one 84 mg capsule whole, twice per day. Take one capsule in the morning and one capsule at night.
- If you are a poor metaboliser: swallow one 84 mg capsule whole, once per day. Take the capsule at the same time each day.

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

5. What should I know while using Cerdelga?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist, pharmacist you visit that you are using Cerdelga.• Provide your Cerdelga Patient Card to any health care professional when seeking treatment.• If you are going to have surgery, tell the surgeon or anaesthetist that you are taking Cerdelga.• Call your doctor straight away if you become pregnant while taking Cerdelga.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly, or lower the dosage, without checking with your doctor.• Avoid grapefruit or grapefruit products since grapefruit may increase the level of Cerdelga in your blood.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how Cerdelga affects you. Cerdelga may cause dizziness in some people.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none">• Store it in a cool dry place away from moisture, heat or sunlight.• Do not store it in the bathroom or near a sink, or in the car or on window sills.

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

6. Are there any side effects?

Common side effects include indigestion, stomach ache, feeling sick (nausea), diarrhoea, constipation, heartburn, bloating, feeling of hard or irregular heart beat, headache, dizziness, tiredness (fatigue), joint pain. In clinical studies, a small number of patients fainted. All of these patients had risk factors for fainting. Tell your doctor straight away if you are feeling faint or you have fainted. 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.

Cerdelga

Active ingredient: *eliglustat*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Cerdelga. **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 Cerdelga.**

Where to find information in this leaflet:

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

1. Why am I using Cerdelga?

Cerdelga contains the active ingredient eliglustat.

Cerdelga belongs to a group of medicines that decrease the production of a substance called glucosylceramide in the body.

Cerdelga is used for the long term treatment of adult patients with Gaucher disease type 1.

Gaucher disease type 1 is a lifelong condition and you must continue to take Cerdelga as prescribed by your doctor to gain the maximum benefit from your medicine.

Gaucher disease type 1 is a rare, inherited condition in which a substance called glucosylceramide builds up in the cells of your spleen, liver and bones. The build-up can prevent these organs from working properly.

Cerdelga decreases the production of glucosylceramide, preventing its build-up. In turn this helps your affected organs to work better.

Some people's bodies break down this medicine faster than others. As a result the amount of this medicine in the blood can differ between patients which could affect how you will respond. Cerdelga is meant to be used in patients whose body breaks down this medicine at normal speed (known as intermediate metaboliser and extensive metaboliser) or slow speed (known as poor metaboliser).

Your doctor will determine if Cerdelga is suitable for you before you start taking it, using a simple laboratory test.

2. What should I know before I use Cerdelga?

Warnings

Do not use Cerdelga if:

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

- you are being treated with any medicines other than Cerdelga until after you have consulted with your doctor. Certain medicines can interfere with your body's ability to breakdown Cerdelga and this can result in higher levels of Cerdelga than needed in your body (see Section [3. What if I am taking other medicines?](#) for an expanded list of medicines).
- you are having any problems with your liver or kidney function until after you have consulted with your doctor. Certain problems with liver or kidney function can result in higher levels of Cerdelga than needed in your body.

Check with your doctor if you:

- are currently taking or are about to start taking any of the medicines listed in Section [3. What if I am taking other medicines?](#)
- are currently taking a medicine for an irregular heart beat (antiarrhythmic medicine), such as quinidine, amiodarone, or sotalol
- have any other medical conditions, including:
 - o liver or kidney problems
 - o heart attack or heart failure
 - o slow heart rate
 - o an irregular, or abnormal heart beat, including a heart condition called long QT syndrome
 - o any other heart problems

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.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is unknown if Cerdelga enters breast milk.

Breastfeeding is not recommended during treatment with this medicine.

Children under the age of 18 years

Do not give Cerdelga to a child under the age of 18 years.

Safety and effectiveness in children have not been established.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you 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.

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

Cerdelga must not be used with certain types of medicines. These medicines can interfere with your body's ability to break down Cerdelga and this can result in higher levels of Cerdelga in your blood.

Medicines that must not be taken in combination with each other and Cerdelga include:

- strong or moderate CYP2D6 inhibitors
- strong or moderate CYP3A inhibitors

There are many medicines in these categories and depending on how your body breaks down Cerdelga, the effects may differ from person to person.

Please speak to your doctor about these medicines before you start taking Cerdelga. Your doctor will determine which medicines you can use based on how fast your body breaks down Cerdelga.

Some medicines may increase the level of Cerdelga in the blood include:

- paroxetine, fluoxetine, fluvoxamine, duloxetine, fluvoxamine, moclobemide – antidepressants used to treat depression
- quinidine, dronedarone, verapamil – antiarrhythmics used to treat irregular heartbeat
- bupropion – used in smoking cessation
- ciclosporin – used in transplant patients
- clarithromycin, erythromycin, ciprofloxacin – antibiotics used to treat infections
- terbinafine, itraconazole, fluconazole, posaconazole, voriconazole – antifungals used to treat fungal infections
- mirabegron – used to treat overactive bladders
- cinacalcet – calcimimetic used in some dialysis patients and specific cancers
- atazanavir, darunavir, fosamprenavir, elvitegravir, indinavir, lopinavir, ritonavir, saquinavir, telaprevir, tipranavir – antiretrovirals used to treat HIV
- cobicistat – used to improve the effects of antiretrovirals (used to treat HIV)
- aprepitant – antiemetic used to reduce vomiting
- diltiazem – antihypertensive used to increase blood flow and decrease heart rate
- boceprevir, telaprevir – antiviral used to treat Hepatitis C
- imatinib – anticancer used to treat cancer
- amlodipine, ranolazine – used to treat angina pectoris
- cilostazol – used to treat cramp-like pain in your legs when you walk caused by insufficient blood supply in your legs
- isoniazid – an antibiotic used to treat tuberculosis
- cimetidine, ranitidine – antacids used to treat indigestion
- goldenseal (also known as *Hydrastis canadensis*) – a herbal preparation obtained without a prescription, used as a digestive aid.

Some medicines may decrease the level of Cerdelga in the blood include:

- rifampicin, rifabutin – antibiotics used to treat infections

- carbamazepine, phenobarbital, phenytoin – anti-epileptics used to treat epilepsy and seizures
- St. John's wort (also known as *Hypericum perforatum*) – a herbal preparation obtained without a prescription, used to treat depression and other conditions.

Cerdelga may increase the level of the following types of medicines in the blood:

- dabigatran – anticoagulant used to thin the blood
- phenytoin – anti-epileptic used to treat epilepsy and seizures
- nortriptyline, amitriptyline, imipramine, desipramine – antidepressants used to treat depression
- flecainide and propafenone – antiarrhythmics used to treat irregular heartbeat
- phenothiazines – antipsychotics used to treat schizophrenia and psychosis
- digoxin – used to treat heart failure and atrial fibrillation
- colchicine – used to treat gout
- metoprolol – used to lower blood pressure and/or reduce heart rate
- dextromethorphan – cough medicine
- atomoxetine – used to treat attention deficit hyperactivity disorder (ADHD)
- pravastatin – used to lower cholesterol and prevent heart disease

These medicines will be affected by Cerdelga or may affect how Cerdelga works. You may need different amounts of your medicines, or take different medicines.

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

4. How do I use Cerdelga?

How much to take

If you are an intermediate metaboliser or extensive metaboliser:

- Swallow one 84 mg capsule whole twice per day. Take one capsule in the morning and one capsule at night.
- Follow the instructions provided and use Cerdelga until your doctor tells you to stop.

If you are a poor metaboliser:

- Swallow one 84 mg capsule whole once per day. Take the capsule at the same time every day.
- Follow the instructions provided and use Cerdelga until your doctor tells you to stop.

Your doctor may have prescribed a different dose. If you have liver problems and/or you are taking other medicines, you should consult with your doctor.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

How to take it

- It may be taken with or without food.
- Swallow the capsules whole with a full glass of water.

- Do not open, crush, dissolve, or chew capsule before swallowing. If you cannot swallow the capsule whole, tell your doctor.
- Avoid grapefruit or grapefruit products since grapefruit may increase the level of Cerdelga in your blood.

When to take Cerdelga

- Take Cerdelga at about the same time each morning and night. Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

If you forget to take Cerdelga

Cerdelga should be used regularly at the same time each day.

If you miss your dose at the usual time, do not take a double dose to make up for the dose that you missed.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

If there is still a long time to go before your next dose, take it as soon as you remember, and then go back to taking it as you would normally.

If you take too much Cerdelga

If you think that you have taken too much Cerdelga, you may need urgent medical attention. Symptoms of an overdose may include: dizziness marked by loss of balance, slow heart rate, nausea, vomiting and light-headedness.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Cerdelga?

Things you should do

Call your doctor straight away if you:

- become pregnant while taking this medicine

Remind any doctor, dentist or pharmacist you visit that you are using Cerdelga.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking Cerdelga. It may affect other medicines used during surgery.

Remember to provide your Cerdelga Patient Card to any health care professional when seeking treatment.

Things you should not do

- Do not stop taking this medicine suddenly, or lower the dosage, without checking with your doctor.

- Avoid grapefruit or grapefruit products since grapefruit may increase the level of Cerdelga in your blood.

Driving or using machines

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

Cerdelga may cause dizziness in some people.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Keep your capsules in the pack until it is time to take them.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

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
Gut related: <ul style="list-style-type: none"> • indigestion • stomach ache • feeling sick (nausea) • diarrhoea • constipation • heartburn • bloating Heart related: <ul style="list-style-type: none"> • feeling of hard or irregular heart beat Head related: <ul style="list-style-type: none"> • headache Muscle, bone or joint related: <ul style="list-style-type: none"> • joint pain General: <ul style="list-style-type: none"> • dizziness 	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
<ul style="list-style-type: none"> tiredness (fatigue) 	

These are the more common side effects of Cerdelga.

Cough has also been reported by patients who use Cerdelga.

In clinical studies, a small number of patients fainted. All of these patients had risk factors for fainting. Please tell your doctor immediately if you are feeling faint or you have fainted.

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 Cerdelga contains

Active ingredient (main ingredient)	Each capsule contains 84 mg of the active ingredient, eliglustat (as tartrate).
Other ingredients (inactive ingredients)	lactose monohydrate microcrystalline cellulose hypromellose glycerol dibehenate The ingredients of the capsule shell are: gelatin candurin silver fine (E555 and E171) iron oxide yellow (E172) indigo carmine (E132) The ingredients of the printing ink are: shellac glaze iron oxide black (E172) propylene glycol ammonium hydroxide

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

What Cerdelga looks like

Cerdelga capsules have a pearl blue-green opaque cap and a pearl white opaque body with "GZ02" printed in black on the capsule.

Each carton contains 56 hard capsules in 4 blister wallets of 14 capsules each (Aust R 218172).

Who distributes Cerdelga

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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