Cerdelga®

eliglustat

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Cerdelga. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

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

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

Keep this leaflet with the medicine.
You may need to read it again.

What Cerdelga is used for

Cerdelga contains the active substance eliglustat. It 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 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.

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.

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

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

There is not enough information to recommend the use of this medicine for children under the age of 18 years.

Before you take it

When you must not take it

Do not take Cerdelga if you:

- are allergic to eliglustat or any of the other ingredients listed at the end of this leaflet.
  Some symptoms of an allergic reaction include skin rash, hives, itching, shortness of breath or swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.
- 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 the section 'Taking other medicines' for an expanded list of medicines).

Do not give Cerdelga to a child under the age of 18 years.
Safety and effectiveness in children have not been established.

Do not take it after the expiry date (exp) printed on the pack or if the packaging is torn or shows signs of tampering.
If it has expired or is damaged return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

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

Tell your doctor immediately if you:

- are currently treated or about to start treatment with any of the medicines listed in section 'Taking other medicines'
- have had a heart attack or heart failure
- have a slow heart rate
- have an irregular, or abnormal heart beat, including a heart

condition called long QT syndrome
- have any other heart problems
- are taking an antiarrhythmic medicine (for irregular heart beats) like quinidine, amiodarone, sotalol.

If you are unsure about whether you should take Cerdelga with your current medicines, check with your doctor or pharmacist.

Tell your doctor if you are or intend to become pregnant.
Your doctor will discuss with you the risks and benefits involved.

Tell your doctor if you are breastfeeding or planning to breastfeed.
It is unknown if Cerdelga enters breast milk. Breast-feeding is not recommended during treatment with this medicine.

If you have not told your doctor about any of the above, tell him/her before you take Cerdelga.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Medicines that must not be taken in combination with each other and Cerdelga:
Cerdelga must not be used with certain type 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. These medicines are known as strong or moderate CYP2D6 inhibitors and 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:

- paroxetine, fluoxetine, duloxetine, bupropion, moclobemide - antidepressants used to treat depression
- quinidine, dronedarone, verapamil - antiarrhythmics used to treat irregular heartbeat
- 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, 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 - antiviral used to treat Hepatitis C
- imatinib - anticancer used to treat cancer
- amlopidine - 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

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

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

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
- nortryptyline, amitriptyline, imipramine - antidepressants used to treat depression
- 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.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Cerdelga.

How to take it

Follow all directions given to you by your doctor or pharmacist carefully and always take this medicine exactly as your doctor or pharmacist has told you.

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.

If you are a poor metaboliser:
Swallow one 84 mg capsule whole once per day. Take the capsule at the same time every day.

Your doctor may have prescribed a different dose.

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 it

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.

How long to take it

Continue taking your medicine for as long as your doctor or pharmacist tells you.

The medicine helps control your condition, but it does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

Do not take a double dose to make up for the dose that you missed.
This may increase the chance of you getting an unwanted side effect.

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 are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Cerdelga. Do this even if there are no signs of discomfort or poisoning.
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.

While you are taking it

Things you must do

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Cerdelga. Remember to provide your Cerdelga Patient Card to any health care professional when seeking treatment.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking 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.

If you become pregnant while taking this medicine, tell your doctor or pharmacist immediately.

Things you must not do

Do not take more than the recommended dose unless your doctor tells you to.

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not use this medicine to treat any other complaints unless your doctor tells you to.

Do not stop taking Cerdelga, or lower the dosage, without checking with your doctor.

Do not start taking any new medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop without consulting your doctor or pharmacist.

Things to be careful of

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

Side effects

All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor or pharmacist has weighed the risks of using this medicine against the benefits they expect it will have for you.

Do not be alarmed by this list of possible side effects.
You may not experience any of them.

Tell your doctor or pharmacist as soon as possible if you do not feel

well while you are taking Cerdelga.

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

- headache
- feeling sick (nausea)
- diarrhoea
- stomach pain
- wind (flatulence)
- joint pain
- tiredness (fatigue)

These are the more common side effects of 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 is making you feel unwell.
Other side effects not listed above may occur in some people.

Do not be alarmed by this list of possible side effects.
You may not experience any of them.

After taking it

Storage

Keep your capsules in the pack until it is time to take them.
If you take the capsules out of the pack they may not keep well.

Keep the medicine in a cool dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom or near a sink. Do not leave it in the car on hot days or on window sills.

Keep it where children cannot reach it.

Disposal

If your doctor or pharmacist tells you to stop taking Cerdelga or the expiry date has passed, ask your pharmacist what to do with any capsules that are left over.

Return any unused medicine to your pharmacist.

Product description

What it 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.

Ingredients

Active ingredient:
Each capsule contains 84 mg of the active ingredient, eliglustat (as tartrate).

Inactive ingredients:
Lactose, microcrystalline cellulose, hypromellose, glycerol dibehenate.

The ingredients of the capsule shell are: gelatin, candurin silver fine (E555 and E171), iron oxide yellow (E172) and indigo carmine (E132).

The ingredients of the printing ink are: shellac glaze, iron oxide black (E172), propylene glycol and ammonium hydroxide.

Supplier

Cerdelga® is supplied in Australia by:

sanofi-aventis australia pty ltd
12-24 Talavera Road
Macquarie Park NSW 2113

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