

**Package leaflet: Information for the patient**  
**Cerdelga 84 mg hard capsules**  
 eliglustat

**Is this leaflet hard to see or read?**  
**Phone 0800 035 2525 for help**

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**

1. What Cerdelga is and what it is used for
2. What you need to know before you take Cerdelga
3. How to take Cerdelga
4. Possible side effects
5. How to store Cerdelga
6. Contents of the pack and other information

**1. What Cerdelga is and what it is used for**

Cerdelga contains the active substance eliglustat and is used for the long-term treatment of adults and children 6 years and older who weigh at least 25 kg with Gaucher disease type 1.

When used in children, Cerdelga is meant for those children whose disease is under control using enzyme replacement therapy. The doctor will determine if Cerdelga is suitable for you or your child before you start taking it, using a simple laboratory test.

Gaucher disease type 1 is a rare, inherited condition in which a substance called glucosylceramide is not effectively broken down by your body. As a result, glucosylceramide builds up in your spleen, liver and bones. The build-up prevents these organs from working properly. Cerdelga contains the active substance eliglustat which decreases the production of glucosylceramide, thereby preventing its build-up. In turn this helps your affected organs to work better.

People differ in the speed that their body breaks down this medicine. As a result, the amount of this medicine in the blood can differ between patients which could affect how a patient would respond. Cerdelga is meant to be used in patients whose body breaks down this medicine at normal speed (known as intermediate metabolisers and extensive metabolisers) or slow speed (known as poor metabolisers).

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

**2. What you need to know before you take Cerdelga**

**Do not take Cerdelga**

- If you are allergic to eliglustat or any of the other ingredients of this medicine (listed in section 6).
- If you are an intermediate or extensive metaboliser and use medicines known as strong or moderate CYP2D6 inhibitors (examples are quinidine and terbinafine) used in combination with strong or moderate CYP3A inhibitors (examples are erythromycin and itraconazole). The combination of these medicines will interfere with your body's ability to break down Cerdelga and this can result in higher levels of the active substance in your blood (see the section 'Other medicines and Cerdelga' for an expanded list of medicines).
- If you are a poor metaboliser and use medicines known as strong CYP3A inhibitors (for example itraconazole). Medicines of this type will interfere with your body's ability to break down Cerdelga and this can result in higher levels of the active substance in your blood (see the section 'Other medicines and Cerdelga' for an expanded list of medicines).
- If you are an extensive metaboliser and you have severely reduced liver function.
- If you are an extensive metaboliser and you have mildly or moderately reduced liver function while taking a strong or moderate CYP2D6 inhibitor.

**Warnings and precautions**

Talk to your doctor or pharmacist before taking Cerdelga if you:

- are currently treated, or about to start treatment with any of the medicines listed in section 'Other medicines and Cerdelga'.
- have had a heart attack or heart failure.
- have a slow heart rate.
- have an irregular, or abnormal heartbeat, including a heart condition called long QT syndrome.
- have any other heart problems.
- are taking an antiarrhythmic medicine (used to treat irregular heartbeat) like quinidine, amiodarone or sotalol.
- are an extensive metaboliser and you have moderately reduced liver function.
- are an intermediate or poor metaboliser and you have any level of reduced liver function.
- are an intermediate or poor metaboliser and you have reduced kidney function.
- are an end stage renal disease (ESRD) patient.

**Children and adolescents**

Cerdelga is not intended for use in children under 6 years of age or weighing less than 25 kg.

**Other medicines and Cerdelga**

Tell your doctor or pharmacist if you are using, have recently used, or might use any other medicines.

**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 regarding these medicines before you start taking Cerdelga. Your doctor will determine which medicines you can use based on how fast your body breaks down eliglustat.

**Medicines that may increase the level of Cerdelga in the blood such as:**

- paroxetine, fluoxetine, fluvoxamine, duloxetine, bupropion, moclobemide – **antidepressants** (used to treat depression)
- dronedarone, quinidine, verapamil – **antiarrhythmic medicines** (used to treat irregular heartbeat)
- ciprofloxacin, clarithromycin, erythromycin, telithromycin – **antibiotics** (used to treat infections)
- terbinafine, itraconazole, fluconazole, posaconazole, voriconazole – **antifungals** (used to treat fungal infections)
- mirabegron – used to treat overactive bladder
- cinacalcet – **calcimimetic** (used in some dialysis patients and specific cancers)
- atazanavir, darunavir, fosamprenavir, indinavir, lopinavir, ritonavir, saquinavir, 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)
- conivaptan – **diuretic** (used to increase low blood sodium levels)
- 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 – 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.

**Medicines that 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 – (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)
- 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**

**Taking Cerdelga with food and drink**

Avoid consumption of grapefruit or grapefruit juice since it may increase the level of Cerdelga in your blood.

**Pregnancy, breast-feeding and fertility**

If you are pregnant, think that you may be pregnant or are planning to have a baby, tell your doctor who will discuss with you whether you can take this medicine during your pregnancy.

The active substance in this medicine has been shown to pass in trace amounts into breast milk in animals. Breast-feeding is not recommended during treatment with this medicine. Tell your doctor if you are breast-feeding.

There are no known effects on fertility at normal doses.

**Driving and using machines**

Cerdelga may affect the ability to drive and use machines in patients who experience dizziness after its administration.

**Cerdelga contains lactose**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

**3. How to take Cerdelga**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Cerdelga is to be taken orally in children who can swallow intact capsule.

Cerdelga hard capsules should be taken whole with water at the same time every day. It may be taken with or without food. Those on twice daily dosing should take one dose in the morning and one dose at night.

Do not open, crush, dissolve, or chew the hard capsule before swallowing it. If you cannot swallow the capsule whole, tell your doctor.

Mixing the content of the capsule (eliglustat powder) into food or drinks has not been studied.

**Recommended dose for adults**

If you are an intermediate metaboliser or extensive metaboliser:

Swallow one 84 mg capsule whole twice a day with water. It may be taken with or without food. Take one capsule in the morning and one capsule at night.

If you are a poor metaboliser:

Swallow one 84 mg capsule whole once a day with water. It may be taken with or without food. Take one capsule at the same time every day.

**Recommended dose for children**

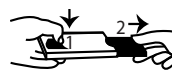
The amount of this medicine your child takes depends on their body weight and on how they metabolise the medicine. The doctor will determine this before starting treatment.

Weight	If your child is an intermediate or extensive metaboliser	If your child is a poor metaboliser
At or over 50 kg	One 84 mg (blue-green and white) capsule twice a day	One 84 mg (blue-green and white) capsule once daily
25 kg to less than 50 kg	One 84 mg (blue-green and white) capsule twice a day	Dose not available

Continue taking Cerdelga every day for as long as your doctor tells you.

**How to pull the blister/wallet from the sleeve for 84 mg hard capsule**

While pressing your thumb and finger together at one end of the sleeve (1) gently pull the blister/wallet out to open the sleeve (2).



**If you take more Cerdelga than you should**

If you take more capsules than you were told to, consult your doctor immediately. You may experience dizziness marked by loss of balance, slow heart rate, nausea, vomiting and light-headedness.

**If you forget to take Cerdelga**

Take the next capsule at the usual time. Do not take a double dose to make up for a forgotten dose.

**If you stop taking Cerdelga**

Do not stop taking Cerdelga without talking to your doctor.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

**4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Common** (may affect up to 1 in 10 people):

- Headache
- Dizziness
- Change in taste (dysgeusia)
- Palpitations
- Throat irritation
- Cough
- Heartburn (dyspepsia)
- Stomach ache (upper abdominal pain)
- Diarrhoea
- Feeling sick (nausea)
- Constipation
- Abdominal pain
- Acid reflux disease (gastroesophageal reflux disease)
- Bloating (abdominal distension)
- Inflammation of the stomach (gastritis)
- Difficulty swallowing (dysphagia)
- Vomiting
- Dry mouth
- Gas (flatulence)
- Dry skin
- Hives (urticaria)
- Joint pain (arthralgia)
- Pain in arms, legs or back
- Tiredness (fatigue)

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Cerdelga**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton, sleeve and blister/wallet after 'EXP'. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

**6. Contents of the pack and other information**

**What Cerdelga contains**

The active substance is eliglustat (as tartrate).

Each hard capsule contains 84 mg of eliglustat.

The other ingredients are:

- In the capsule: cellulose, microcrystalline (E460), lactose monohydrate (see section 2 under 'Cerdelga contains lactose'), hypromellose and glycerol dibehenate.
- In the capsule shell: gelatin (E441), potassium aluminium silicate (E555), titanium dioxide (E171), yellow iron oxide (E172) and indigotine (E132).
- In the printing ink: shellac, black iron oxide (E172), propylene glycol (E1520) and ammonia solution, concentrated (E527).

**What Cerdelga looks like and contents of the pack**

Cerdelga 84 mg hard capsules have a pearl blue-green opaque cap and a pearl white opaque body with "GZ02" printed in black on the capsule.

Pack sizes of 14 hard capsules in 1 blister wallet, 56 hard capsules in 4 blister wallets of 14 capsules each or 196 hard capsules in 14 blister wallets of 14 capsules each.

Not all packs may be marketed.

**Marketing Authorisation Holder and Manufacturer**

Marketing Authorisation Holder

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This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

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