PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

Cerdelga, Hard Capsules

Composition: Each hard capsule contains active substance: Eliglustat (as tartrate) 84.4 mg
Each capsule also contains: lactose monohydrate 111.5 mg
Inactive ingredients: see section 6.

Read this leaflet carefully in its entirety before using the medicine.
Keep this leaflet, you may need to read it again.
This leaflet contains concise information about the medicine.
If you have further questions, refer to the doctor or pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

In addition to the leaflet, Cerdelga also has a Patient Safety Information Card. This card contains important safety information that you must know and abide by before starting and during treatment with Cerdelga. Read the Patient Safety Information Card and the Patient Leaflet before commencing use of the preparation. Keep the card for further reading, if necessary.

This medicine is intended for adults over the age of 18.

1. WHAT IS THE MEDICINE INTENDED FOR?

Cerdelga is a medicine used for long-term treatment of adult patients with Gaucher disease type 1.
Gaucher disease type 1 is a rare, inherited disease in which a substance called glucosylceramide is not effectively broken down in the body. As a result, glucosylceramide builds up in the 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, the treatment helps the affected organs work better.
People differ in the speed that their body breaks down this medicine. As a result, the amount of medicine in the blood can differ from patient to patient, which could affect how a patient would respond. Cerdelga is meant to be used in patients whose body breaks down this medicine at a normal speed (known as intermediate metabolisers or extensive metabolisers) or a slow speed (known as poor metabolisers). The doctor will determine if Cerdelga is suitable for you before you start taking the medicine, using a simple laboratory test.
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.

Therapeutic group: Inhibitor of the enzyme glucosylceramide synthase, which affects metabolism in the body.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to eliglustat or to any of the other ingredients of this medicine (see section 6).
- If you are an intermediate or extensive metaboliser and you use medicines known as strong or moderate CYP2D6 inhibitors (e.g., quinidine and terbinafine) in combination with strong or moderate CYP3A inhibitors (e.g., 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 in section "Other medicines and Cerdelga" an expanded list of medicines).
- You are a poor metaboliser and you use medicines known as strong CYP3A inhibitors (e.g., 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 in section "Other medicines and Cerdelga" an expanded list of medicines).
- You are an extensive metaboliser and you have severely impaired liver function.
- You are an extensive metaboliser and you have mildly or moderately impaired liver function while you are taking strong or moderate CYP2D6 inhibitor.

Special warnings regarding use of the medicine
Before treatment with Cerdelga, tell the doctor if:

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

Children and adolescents
Cerdelga has not been tested in children and adolescents under the age of 18. Do not give this medicine to children or adolescents.

Other medicines and Cerdelga: If you are taking, have recently taken, or plan to take other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist, especially for:

Medicines that must not be taken in combination with each other and with Cerdelga
Cerdelga must not be used with certain 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. 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** (to treat depression)
- dronedarone, quinidine, verapamil - **antiarrhythmics** (to treat irregular heartbeat)
- ciprofloxacin, clarithromycin, erythromycin, telithromycin - **antibiotics** (to treat infections)
- terbinafine, itraconazole, fluconazole, posaconazole, voriconazole - **antifungals** (to treat fungal infections)
- mirabegron - to treat overactive bladder
- cinacalcet - **calcimimetic** (used in some dialysis patients and specific cancers)
- atazanavir, darunavir, fosamprenavir, indinavir, lopinavir, ritonavir, saquinavir, tipranavir - **antiretrovirals** (to treat HIV)
- cobicistat - used to improve the effects of antiretrovirals (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 - **antivirals** (used to treat hepatitis C)
- imatinib - a medicine 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 the legs
- isoniazid - used to treat tuberculosis
- cimetidine, ranitidine - **antacids** (used to treat indigestion)
- goldenseal - (also known as *Hydrastis canadensis*) a non-prescription herbal preparation, 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 non-prescription herbal preparation, 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.**

Use of the medicine and food
Avoid consumption of grapefruit and grapefruit juice since it may increase the level of Cerdelga in your blood.

Pregnancy, breastfeeding and fertility
If you are pregnant, think that you may be pregnant or are planning to have a baby, tell the doctor, who will discuss with you whether you can take this medicine during pregnancy.
The active substance in this medicine has been shown to pass in trace amounts into breast milk in animals. Breastfeeding is not recommended during the course of treatment with this medicine. Talk to your doctor if you are breastfeeding.
There are no known effects on fertility at normal dosages.

Driving and using machines
Cerdelga has a negligible or no influence on the ability to drive or operate machines.

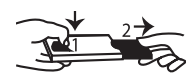
Important information about some of the ingredients of the medicine
Cerdelga contains lactose
If you have been told by the doctor that you have an intolerance to some sugars, contact him before taking this medicine.

3. HOW SHOULD YOU USE THE MEDICINE

Always use this medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure regarding the dosage and treatment regimen of the preparation.

Dosage and instructions for use
The dosage and treatment regimen will be determined by the doctor only.
Cerdelga is a medicine taken orally. The recommended dosage is:
If you are an intermediate metaboliser or extensive metaboliser:
Swallow one whole capsule, twice a day with water. It may be taken with or without food, one capsule in the morning and one capsule at night.
If you are a poor metaboliser:
Swallow one whole capsule, once a day with water. It may be taken with or without food, one capsule at the same time every day.
Do not exceed the recommended dose.
Do not open, crush, dissolve, or chew the capsule before swallowing it. If you cannot swallow the capsule whole, consult the doctor.
Continue taking Cerdelga every day for as long as the doctor tells you.

How to pull the blister/wallet from the sleeve
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 accidentally take a higher dosage
If you take more capsules than you were told to, consult the doctor immediately. You may experience dizziness marked by loss of balance, slow heart rate, nausea, vomiting and light headedness.
If you took an overdose or if a child accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forget to take the medicine
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 the medicine
Do not stop taking Cerdelga without consulting the doctor. Adhere to the treatment regimen as recommended by the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them. If you have further questions regarding use of this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Cerdelga may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Common side effects effects that occur in 1-10 in 100 users:

- Headache
- Dizziness
- Change in taste (dysgeusia)
- Pounding heart (palpitations)
- Throat irritation
- Cough
- Heartburn (dyspepsia)
- Feeling sick (nausea)
- Diarrhoea
- Constipation
- Abdominal pain, stomach ache
- Acid reflux disease (gastroesophageal reflux disease)
- Bloating (abdominal distention)
- 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)

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor

Reporting side effects
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: http://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED

Avoid poisoning! This medicine, and any other medicine, must be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
Do not use this medicine after the expiry date (Exp. Date) that appears on the package. The expiry date refers to the last day of that month.
Store in the original package. Store below 30°C.
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. FURTHER INFORMATION

In addition to the active substance, Cerdelga also contains:
In the capsule: lactose monohydrate, microcrystalline cellulose, hypromellose and glycerol dibehenate.
In the capsule shell: gelatin, potassium aluminium silicate, titanium dioxide, yellow iron oxide, indigotine.
In the printing ink: shellac glaze, black iron oxide (E172), propylene glycol, ammonium hydroxide.

What the medicine looks like and the contents of the package
The Cerdelga capsule has 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.
Not all package sizes may be marketed.

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

License holder and address: Sanofi Israel Ltd., Greenwork Park, P.O. box 47, Yakum.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 1575634703.

Revised in September 2023 according to MOH guidelines.