

## PATIENT MEDICATION INFORMATION

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

#### **Pr**CERDELGA™ Eliglustat Capsules

Read this carefully before you start taking **CERDELGA** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **CERDELGA**.

#### **What is CERDELGA used for?**

CERDELGA is used to treat adults, with Gaucher disease type 1, who:

- process CERDELGA at a regular speed (extensive metabolizers or EMs).
- process CERDELGA at a slower speed (intermediate metabolizers or IMs).
- process CERDELGA at a very slow speed (poor metabolizers or PMs).

Your healthcare professional will perform a test to make sure that CERDELGA is right for you. This test will tell your healthcare professional how quickly your body processes (metabolizes) CERDELGA. It will also determine if and how you can use this medicine.

#### **How does CERDELGA work?**

Gaucher disease type 1 is caused by not having the normal amount of an enzyme called acid  $\beta$ -glucosidase. This enzyme's job is to break down a lipid, or fatty substance, in your body called glucosylceramide. CERDELGA lowers the production of a lipid called glucosylceramide in the body. This helps the organs, like your liver and spleen, to work better.

Gaucher disease type 1 is a lifelong condition. You must continue to take CERDELGA as prescribed by your healthcare professional.

#### **What are the ingredients in CERDELGA?**

Medicinal ingredients: eliglustat (as eliglustat tartrate)

Non-medicinal ingredients: ammonium hydroxide, black iron oxide (E172), gelatin, glyceryl behenate/glycerol dibehenate, hypromellose, indigotine (E132), lactose monohydrate, microcrystalline cellulose, propylene glycol, shellac glaze, candurin silver fine, yellow iron oxide (E172) and potassium aluminum silicate (E555)

#### **CERDELGA comes in the following dosage forms:**

Capsules; 84 mg

#### **Do not use CERDELGA if:**

- you are allergic to eliglustat tartrate or any of the other ingredients of CERDELGA or the container
- you have one of the following rare genetic disorders, because lactose is a non-medicinal ingredient in CERDELGA:
  - Galactose intolerance

- Lapp lactase deficiency
- Glucose-galactose malabsorption
- are an **extensive or intermediate metabolizer**, and
  - you are taking a combination of other medicines called **strong or moderate CYP2D6 inhibitors** with **strong or moderate CYP3A inhibitors**. The combination of these types of medicine will affect how you respond to CERDELGA.
- are an **intermediate or poor metabolizer**, and
  - you are taking medicines that are **strong CYP3A inhibitors**. Medicines of this type will affect how you respond to CERDELGA, or
  - you have liver problems.
- are an **extensive metabolizer** and you also have one of the following:
  - moderate to severe liver problems, or
  - mild liver problems and you are taking a **strong or moderate CYP2D6 inhibitor**, or
  - mild liver problems and you are taking a **strong CYP3A inhibitor**

Examples of **strong or moderate CYP2D6 inhibitors** are paroxetine, fluoxetine, quinidine, bupropion or terbinafine, duloxetine, moclobemide, mirabegron, cinacalcet and dronedarone.

Examples of **moderate CYP3A inhibitors** are cobicistat, indinavir, fluconazole, erythromycin, ciprofloxacin, diltiazem, verapamil, aprepitant, atazanavir, darunavir, fosamprenavir, imatinib and cimetidine.

Examples of **strong CYP3A inhibitors** are ketoconazole, clarithromycin, itraconazole, lopinavir, ritanovir, saquinavir, cobicistat, indinavir, telaprevir, tipranavir, posaconazole, voriconazole, conivaptan and boceprevir.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take CERDELGA. Talk about any health conditions or problems you may have, including if you:**

- Have heart problems like heart failure, heart disease, history of a heart attack.
- Have a family history of sudden cardiac death before age 50 years.
- Have a history of fainting.
- Have an irregular or abnormal heartbeat, including a heart condition called long QT syndrome.
- Have kidney or liver problems.
- Have an eating disorder.
- Have low blood levels of potassium, magnesium, or calcium.
- Are dehydrated or suffer from excessive vomiting, diarrhea or sweating.
- Are pregnant, think that you may be pregnant or are planning to become pregnant. You must talk to your healthcare professional about whether you can take CERDELGA while you are pregnant.
- Are breast-feeding or planning to breastfeed. It is not known if CERDELGA passes into your breast milk. You and your healthcare professional will decide if you should take CERDELGA or breastfeed. You should not do both.
- If you are 65 years old or older.

**Check-ups and testing:** You will have regular visits with your healthcare professional during your

treatment. These visits might include the following to monitor your health:

- electrocardiogram (ECG) to monitor your heart rhythm health.
- blood tests

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with CERDELGA:**

- Medicines used to treat fungal infections (such as ketoconazole, fluconazole, terbinafine, itraconazole, posaconazole, voriconazole, amphotericin B)
- Medicines used to treat bacterial infections (such as clarithromycin, erythromycin, ciprofloxacin, moxifloxacin, levofloxacin, telithromycin, tacrolimus)
- Medicines used to treat malaria (such as quinine, chloroquine)
- Medicines used to treat HIV infection and AIDS (such as cobicistat, indinavir, lopinavir, ritonavir, saquinavir, telaprevir, tipranavir, atazanavir, darunavir, fosamprenavir)
- Medicines used to treat Hepatitis C infection (boceprevir)
- Medicines used to treat tuberculosis (such as rifampin, isoniazid, rifabutin)
- Medicines used to treat seizures (such as carbamazepine, phenobarbital, phenytoin)
- Medicines used for heart conditions or high blood pressure (such as quinidine, dronedarone, diltiazem, verapamil, amlodipine, digoxin, metoprolol)
- Medicines used to treat depression or other mental health problems (such as paroxetine, fluoxetine, bupropion, duloxetine, moclobemide, fluvoxamine, perphenazine, chlorpromazine, pimozide, haloperidol, droperidol, risperidone, ziprasidone, citalopram, venlafaxine, nortriptyline, amitriptyline, imipramine, desipramine, maprotiline, atomoxetine)
- Medicines used to treat overactive bladder (such as mirabegron)
- Medicines used to prevent nausea and vomiting (such as ondansetron, aprepitant)
- Medicines used to treat cancer (such as imatinib, sunitinib, nilotinib, vandetanib, vorinostat)
- Medicines used to treat breathing problems like asthma (such as salmeterol, formoterol)
- Medicines used to treat low levels of sodium in the blood (such as conivaptan)
- Medicines used to treat problems with the parathyroid gland (such as cinacalcet)
- Medicines used to treat gout (such as colchicine)
- Medicines used to treat cough (such as dextromethorphan)
- Medicines used to prevent stroke (such as dabigatran)
- Medicines used to treat high cholesterol levels (such as pravastatin)
- Medicines used to treat pneumonia caused by fungus (such as pentamidine)
- Medicine used to treat ulcers (cimetidine, ranitidine)
- Medicine to treat heartburn and acid reflux (such as proton pump inhibitors)
- St. John's wort, an herbal medicine used to treat depression
- Goldenseal, an herbal medicine used to treat the common cold
- Laxatives and enemas
- High dose corticosteroids used to treat inflammation and reduce the activity of the immune system
- Opioids (such as methadone)
- Domperidone, often used to increase milk supply in women who are breastfeeding
- Diuretics or "water pills"

- Grapefruit. Do not eat grapefruit or drink grapefruit juice since it may increase the level of CERDELGA in your blood.

If you take any medicines for the conditions listed above, your healthcare professional may need to prescribe a different medicine, change your dose of the other medicines, or change your dose of CERDELGA.

**How to take CERDELGA:**

- Always take CERDELGA exactly as your healthcare professional has told you. Check with your healthcare professional if you are not sure.
- CERDELGA can be taken with or without food.
- Take CERDELGA at the same time each day.
- Swallow CERDELGA whole with water. Do not open, crush, dissolve, or chew the capsule. If you cannot swallow the capsule whole, tell your healthcare professional.

**Usual dose:**

Your healthcare professional will decide on the dose that is right for you. It may be either one or two CERDELGA capsules per day. This will be based on any other medicines you may be taking and blood tests to determine:

- the type of metabolizer you are (how quickly your body breaks down CERDELGA), and
- if you have kidney or liver problems.

**Overdose:**

Symptoms of taking too much CERDELGA may include dizziness with loss of balance, slow heart rate, nausea, vomiting and light-headedness.

If you think you, or a person you are caring for, have taken too much CERDELGA, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

**Missed Dose:**

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

**What are possible side effects from using CERDELGA?**

These are not all the possible side effects you may have when taking CERDELGA. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- tiredness, sleepiness or drowsiness, low energy
- headache
- dizziness
- fainting
- nausea, diarrhea, gas, indigestion, constipation, stomach pain
- dry mouth, trouble swallowing

- trembling movements
- pain in the bones, chest, arms, legs or back
- cough
- acne, skin marks
- oral fungal infection
- change in taste, smell, touch
- weight or bone loss
- confusion
- flushing
- ringing, buzzing, clicking or hissing in the ears
- irregular periods

CERDELGA can cause abnormal blood test results. Your healthcare professional will decide when these are necessary and will interpret the results. They will tell you if your test results are abnormal and if you need treatment.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>RARE</b>			
<b>Changes in the electrical activity of your heart</b> (ECG changes): palpitations, irregular heartbeat, dizziness, fainting, light headedness, shortness of breath			√

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

#### Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

#### Storage:

- Keep out of reach and sight of children.
- Store at 20°C to 25°C.
- Do not use this medicine after the expiry date which is stated on the carton, sleeve and blister after 'EXP'. The expiry date refers to the last day of that month.

**If you want more information about CERDELGA:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer's website [www.sanofi.ca](http://www.sanofi.ca), or by calling 1-800-265-7927.

This leaflet was prepared by sanofi-aventis Canada Inc.

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