

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**  
**PART III: PATIENT MEDICATION INFORMATION**

**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 a medicine used for treating adult patients with Gaucher disease type 1. **CERDELGA** is not used in certain people with Gaucher disease type 1. Your doctor will perform a test to make sure that **CERDELGA** is right for you. This test will tell how quickly your body breaks down (metabolizes) **CERDELGA**. It will also determine if and how you can use this medicine.

If your body metabolizes **CERDELGA** at a regular speed, you are an **extensive metabolizer**.

If your body metabolizes **CERDELGA** at a slower speed, you are an **intermediate metabolizer**.

If your body metabolizes **CERDELGA** at a very slow speed, you are a **poor metabolizer**.

**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. Because the level of this enzyme is lower in people with Gaucher disease, the lipid builds up in your body. The lipid build up can damage your organs, especially your liver and spleen. **CERDELGA** decreases the production of glucosylceramide which prevents its build-up. This helps the organs affected by Gaucher disease 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 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, titanium dioxide (E171) and yellow iron oxide (E172).

## **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
- have one of the following rare hereditary conditions, because lactose is a non-medical 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:**

- Are currently taking, or are about to start taking any of the medicines described in section 'The following may interact with CERDELGA'.
- Have heart problems.
- Have a history of a heart attack.
- Have a family history of sudden cardiac death before age 50 years.

- Have a history of fainting (syncope).
- Have an irregular or abnormal heart beat, 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.

**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:**

CERDELGA must not be used with certain types of medicines. Some medicines can interfere with your body's ability to break down CERDELGA, resulting in higher levels of CERDELGA in your blood. These medicines are known as strong, moderate or weak CYP2D6 inhibitors and strong, moderate, or weak CYP3A inhibitors. Other medicines and herbs can also interact with CERDELGA.

**Especially tell your healthcare professional if you take:**

- St. John's wort (*Hypericum perforatum*), an herbal medicine used to treat depression.
- Goldenseal, an herbal medicine used to treat the common cold.
- Medicine to treat fungal infections (such as ketoconazole, fluconazole, terbinafine, itraconazole, posaconazole, voriconazole, amphotericin B)
- Medicine to treat bacterial infections (such as clarithromycin, erythromycin, ciprofloxacin, moxifloxacin, levofloxacin, telithromycin, tacrolimus)
- Medicine to treat malaria (such as quinine, chloroquine)
- Medicine to treat HIV infection and AIDS (such as cobicistat, indinavir, lopinavir, ritonavir, saquinavir, telaprevir, tipranavir, atazanavir, darunavir, fosamprenavir)
- Medicine to treat Hepatitis C infection (boceprevir)
- Medicine to treat tuberculosis (such as rifampin, isoniazid, rifabutin)
- Medicine to treat seizures (such as carbamazepine, phenobarbital, phenytoin)
- Medicine for heart conditions or high blood pressure (such as quinidine, dronedarone, diltiazem, verapamil, amlodipine, digoxin, metoprolol)
- Medicine 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)

- Medicine to treat overactive bladder (such as mirabegron)
- Opioids (such as methadone)
- Domperidone, often used to increase milk supply in women who are breastfeeding
- Medicine to prevent nausea and vomiting (such as ondansetron, aprepitant)
- Medicine to treat cancer (imatinib, sunitinib, nilotinib, vandetanib, vorinostat)
- Medicine to treat breathing problems like asthma (such as salmeterol, formoterol)
- Diuretics or “water pills”
- Medicine to treat low levels of sodium in the blood (such as conivaptan)
- Medicine to treat problems with the parathyroid gland (such as cinacalcet)
- Medicine to treat gout (such as colchicine)
- Medicine to treat cough (such as dextromethorphan)
- Medicine to prevent stroke (such as dabigatran)
- Medicine to treat high cholesterol levels (such as pravastatin)
- Laxatives and enemas
- High dose corticosteroids used to treat inflammation and reduce the activity of the immune system
- Medicine used to treat ulcers (cimetidine, ranitidine)
- Medicine to treat heartburn and acid reflux (such as proton pump inhibitors)

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. Tell your healthcare professional about any new medicines before you start taking them.

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

**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.
- Continue taking CERDELGA every day for as long as your healthcare professional tells you.
- 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 adult 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:**

If you think you have taken too much CERDELGA, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

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

**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 feel when taking CERDELGA. If you experience any side effects not listed here, contact 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
- tremor
- pain in the arms, legs or back

<b>Serious side effects and what to do about them</b>			
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 (ECG changes):</b> palpitations, irregular heartbeat,			√

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
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dizziness, fainting			

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

<p><b>Reporting Side Effects</b>  You can report any suspected side effects associated with the use of health products to Health Canada by:</p> <ul style="list-style-type: none"> <li>• Visiting the Web page on Adverse Reaction Reporting (<a href="https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html">https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html</a>) for information on how to report online, by mail or by fax; or</li> <li>• Calling toll-free at 1-866-234-2345.</li> </ul> <p><i>NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.</i></p>
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**Storage:**

Keep out of reach and sight of children.

Store at 20°C to 25°C with excursions permitted between 15°C and 30°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.html>); the manufacturer’s website [www.genzyme.ca](http://www.genzyme.ca), or by calling 1-877-220-8918.

This leaflet was prepared by Sanofi Genzyme, a division of sanofi-aventis Canada Inc.

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