

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrZAVESCA®
migLUstat capsules

Read this carefully before you start taking **ZAVESCA** 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 **ZAVESCA**.

What is ZAVESCA used for?

ZAVESCA is used for:

- the treatment of mild to moderate Type 1 Gaucher disease in adults who cannot use imiglucerase (Cerezyme), or enzyme replacement therapy.
- slowing the progression of some of the neurologic symptoms in adults and children 4 years of age and older with Niemann-Pick Type C disease (affecting the brain and nervous system).

How does ZAVESCA work?

ZAVESCA prevents an enzyme called glucosylceramide synthase from working. This reduces the production of fatty substances called glycosphingolipid glucosylceramide in cells.

Type I Gaucher disease is a condition in which there is a build-up of glucosylceramide in certain cells of the body's immune system called macrophages. This results in liver and spleen enlargement, changes in the blood, and bone disease.

In Niemann-Pick Type C disease, glycosphingolipids (fats) build-up in cells in the brain. This can result in problems with eye movement, eye sight (vision), balance, swallowing, speech, and memory, and in seizures (fits).

What are the ingredients in ZAVESCA?

Medicinal ingredients: Miglustat

Non-medicinal ingredients: black iron oxide (E172), gelatin, magnesium stearate, povidone (K30), sodium starch glycolate, shellac, titanium dioxide (E171)

ZAVESCA comes in the following dosage forms:

Capsule: 100 mg

Do not use ZAVESCA if:

- you are allergic to miglustat or to any of the non-medicinal ingredients in ZAVESCA or any component of the container (see What are the ingredients in ZAVESCA?).
- you are pregnant or planning to get pregnant. ZAVESCA may harm your unborn baby.

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

- have or have had kidney problems
- have liver problems
- have stomach or intestine problems, including inflammatory bowel disease (IBD)
- have or have had cataracts (clouding of the lens of your eye)

Other warnings you should know about:

ZAVESCA should only be prescribed by a healthcare professional experienced in the management of patients with Gaucher disease or Niemann-Pick Type C disease.

Pregnancy, Breastfeeding and Fertility:

Female Patients:

- You must not take ZAVESCA if you are pregnant or planning to become pregnant. ZAVESCA can harm your unborn baby. Your healthcare professional will make sure you are not pregnant before you start taking ZAVESCA.
- If you are able to get pregnant you must use an effective method of birth control while you are taking ZAVESCA.
- You should not breastfeed while you are taking ZAVESCA. It is not known if ZAVESCA passes into breastmilk.

Male Patients:

- You should not father a child while taking ZAVESCA and for three months after taking your last dose.
- You must use effective birth control while you are taking ZAVESCA and for 3 months after your last dose. Your female partner should also use an effective method of birth control while you are taking ZAVESCA and for 3 months after your last dose.
- ZAVESCA can affect your sperm and reduce your fertility.

Blood Tests and Monitoring: ZAVESCA can cause abnormal blood test results. Your healthcare professional will decide when to do blood tests and will interpret the results. They will also monitor the health of your spleen and liver. You should have a neurological exam, to check the health of your brain and nerves before you start taking ZAVESCA. This will be repeated by your healthcare professional periodically during treatment.

Driving and Operating Machinery: ZAVESCA may cause dizziness. Give yourself time after taking ZAVESCA to see how you feel before driving a vehicle or using machinery.

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 ZAVESCA:

- There are no known relevant interactions at this time.

How to take ZAVESCA:

- Always take ZAVESCA exactly as your healthcare professional has instructed you. You should check with your healthcare professional if you are unsure.
- Your healthcare professional will decide how long you should take ZAVESCA.
- Your healthcare professional might give you a lower dose if you have kidney problems.
- ZAVESCA capsules should be swallowed whole with water.
- ZAVESCA can be taken with or without food. Your risk of diarrhea may be reduced if you take ZAVESCA between meals.

Usual dose:

Type 1 Gaucher disease:

- **Adults 18 years of age and older:** 100 mg three times daily taken at regular intervals.

Niemann-Pick Type C disease:

- **Adults and adolescents 12 to 17 years of age:** 200 mg three times daily.
- **Children 4 to 12 years old:** Your healthcare professional will decide on the correct dose for your child.

Overdose:

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

Missed dose:

If you forget to take a dose of ZAVESCA, do not take another dose to make up for the missed dose. Take your next dose at the usual time.

What are possible side effects from using ZAVESCA?

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

Side effects may include:

- weight loss
- loss of appetite
- dry mouth
- gas (flatulence)
- stomach pain
- indigestion
- nausea
- constipation
- headache
- dizziness, vertigo
- fatigue
- generalized weakness
- flu-like symptoms

- vision changes
- muscle cramps or spasms
- memory problems

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	
VERY COMMON			
Diarrhea		✓	
COMMON			
Neurological problems: tingling, numbness or pain, loss of reflexes, new tremors or worsening of existing tremors in the hands		✓	
Thrombocytopenia (low levels of platelets in the blood): increased bleeding or bruising, rash with reddish-purple spots, bleeding from the nose or gums, blood in urine or stool		✓	
Convulsions: seizures or fits with or without loss of consciousness			✓

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.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:

- Store at room temperature between 15-30°C
- Protect from moisture
- Store in the original container
- Do not use after the expiry date stated on the container
- Keep out of the sight and reach of children

If you want more information about ZAVESCA:

- 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.janssen.com/canada or by calling: 1-800-567-3331 or 1-800-387-8781.

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