

PART III: CONSUMER INFORMATION

PrZAVESCA
Miglustat capsules
100 mg

This leaflet is part III of a three-part "Product Monograph" published when the drug is approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about ZAVESCA. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATIONWhat this medication is used for:

ZAVESCA is used for:

- the treatment of mild to moderate Type 1 Gaucher disease in adult patients over 18 years of age who cannot use imiglucerase (Cerezyme), or enzyme replacement therapy.
- to slow the progression of some of the neurologic symptoms in patients with Niemann-Pick Type C disease (affecting the brain and nervous system).

What it does:

ZAVESCA (miglustat) prevents an enzyme called glucosylceramide synthase from working, thereby reducing 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).

When it should not be used:

Do not use ZAVESCA if you:

- are allergic to miglustat or any of the other ingredients in ZAVESCA
- are pregnant or planning to get pregnant. ZAVESCA may cause harm to the unborn baby.

What the medicinal ingredient is:

Miglustat

What the nonmedicinal ingredients are:

Capsule contents: magnesium stearate, povidone (K30), sodium starch glycolate

Capsule shell: gelatin, titanium dioxide, water

Printing ink: black iron oxide, potassium hydroxide, propylene glycol, shellac.

What dosage forms it comes in:

Capsule 100 mg

WARNINGS AND PRECAUTIONS

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

Before you use ZAVESCA talk to your doctor or pharmacist if you:

- have or have had kidney problems
- have liver problems
- have gastrointestinal disease, including inflammatory bowel syndrome
- are pregnant or planning to become pregnant. Pregnancy should be ruled out before taking ZAVESCA
- are breastfeeding

Female patients should use a reliable method of contraception while taking ZAVESCA.

Male patients should not father a child while taking ZAVESCA and for three months after taking the last dose of this drug.

Do not drive a car or operate machinery until you know how ZAVESCA affects you. ZAVESCA may cause dizziness.

INTERACTIONS WITH THIS MEDICATION

You should always tell your doctor about all drugs you are taking or plan to take including prescription, non-prescription, vitamins and dietary supplements before starting ZAVESCA.

PROPER USE OF THIS MEDICATION

Always take ZAVESCA exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

ZAVESCA capsules should be swallowed whole with water. The risk of diarrhea may be reduced if ZAVESCA is taken between meals.

Usual dose:**Type 1 Gaucher disease:**

Adult over 18 years of age: 100 mg three times daily taken at regular intervals.

Niemann-Pick Type C disease:

Adults and juveniles: 200 mg three times daily.

Children under 12 years old: the dose is based on body surface area (BSA mg/m²).

If you have a problem with your kidneys you may receive a lower starting dose. If your kidney problem is severe, it is unlikely that your doctor will prescribe ZAVESCA. Your doctor will tell you how long your treatment will last.

Overdose:

If you take more ZAVESCA than you should, contact your doctor, or poison control centre, or emergency room of the nearest hospital immediately.

Missed dose:

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

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

ZAVESCA can have side effects.

Very common side effects: weight loss, diarrhea, dizziness, flatulence, tremor, abdominal (stomach) pain, nausea and headache.

Common side effects: loss of appetite, eating disorder (anorexia), constipation, paresthesia (tingling, pricking, or numbness), generalized weakness, flu like symptoms, discomfort in the stomach (dyspepsia), increased bleeding or bruising (thrombocytopenia), dizziness, vertigo, change in vision, cramps, dry mouth, muscular spasm and tiredness (fatigue).

Serious side effects: neurological problems (neuritis and neuropathy), tremor, numbness or tingling.

Call your doctor if pain, loss of reflexes, tremors, numbness or tingling occur while taking ZAVESCA, or if the hand tremors you already have get worse.

THE KNOWN SERIOUS SIDE EFFECTS ARE DESCRIBED IN THE BOX BELOW, WHICH ALSO TELLS YOU WHAT TO DO ABOUT THEM.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Very common	Diarrhea		✓	
	Weight loss		✓	
	Nausea	✓		
	Abdominal pain	✓		
	Headache	✓		
	Dizziness		✓	
	Flatulence		✓	
	Tremors		✓	
Common	Tingling or numbness or pain		✓	
	Muscle cramps		✓	
	Anorexia		✓	
	Decreased appetite		✓	
	Dyspepsia		✓	
	Constipation		✓	
	Vomiting		✓	
	Cramps		✓	
	Increase bleeding or bruising (thrombocytopenia)		✓	

THIS IS NOT A COMPLETE LIST OF SIDE EFFECTS. IF YOU HAVE ANY UNEXPECTED EFFECTS WHILE TAKING THIS DRUG, CONTACT YOUR DOCTOR OR PHARMACIST.

HOW TO STORE IT

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

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

Report online at www.healthcanada.gc.ca/medeffect

Call toll-free at 1-866-234-2345

Complete a Canada Vigilance Reporting Form and:

- Fax toll-free to 1-866-678-6789, or

- Mail to; Canada Vigilance Program

Health Canada

Postal Locator 070ID

Ottawa, Ontario

K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of the side effect, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: www.janssen.com/canada or by contacting the sponsor, Janssen Inc., at: 1-800-567-3331 or 1-800-387-8781

This leaflet was prepared by Janssen Inc. Toronto, Ontario, M3C 1L9

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