



Healthy Choices

INDICATION AND IMPORTANT SAFETY INFORMATION

What is ZAVESCA® (miglustat)?

ZAVESCA® is a prescription medicine used alone to treat adults with mild to moderate type 1 Gaucher disease. ZAVESCA® is used only in people who cannot be treated with enzyme replacement therapy.

It is not known if ZAVESCA® is safe and effective in children under 18 years of age.

What should I tell my doctor before taking ZAVESCA®?

Before you take ZAVESCA® tell your doctor if you:

- have kidney problems
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if ZAVESCA® will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if ZAVESCA® passes into your breast milk. You and your doctor should decide if you will breastfeed or take ZAVESCA®. You should not do both.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. ZAVESCA® may affect how other medicines work.

Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

How should I take ZAVESCA®?

- Take ZAVESCA® exactly as your doctor has prescribed.
- Take ZAVESCA® at the same time each day.
- If you miss a dose of ZAVESCA®, skip that dose. Take the next ZAVESCA® capsule at the usual time.

What are the possible side effects of ZAVESCA®?

ZAVESCA® may cause serious side effects including:

- **Numbness, tingling, pain, or burning in your hands or feet (peripheral neuropathy).** Call your doctor right away if you get numbness, tingling, pain, or burning in your hands or feet.
- Your doctor may test your nerves (neurological exam) before you start ZAVESCA® and during treatment with ZAVESCA®.
- **New or worsening hand tremors (shaky movements).** Tremors are common with ZAVESCA® and may begin within the first month of starting

treatment. Sometimes the tremors may go away between 1 to 3 months with continued treatment. Your doctor may lower your dose or stop ZAVESCA® if you develop new or worsening hand tremors. Call your doctor right away if you get new hand tremors while taking ZAVESCA® or if the hand tremors you already have get worse.

- **Diarrhea** is common with ZAVESCA® and sometimes can be serious. Your doctor may prescribe another medicine (anti-diarrheal) to treat diarrhea if it is a problem for you and may recommend changes to your diet, such as avoiding foods high in carbohydrates. Talk with your doctor about your diet if you have diarrhea.
- **Weight loss** is common with ZAVESCA® and sometimes can be serious. You may lose weight when you start treatment with ZAVESCA®.
- **Low platelet count** is common with ZAVESCA® and can be serious. Your doctor may do blood tests to monitor your blood platelet count.

The most common side effects of ZAVESCA® are:

- | | |
|--------------------------------|---|
| • Weight loss | • Dry mouth |
| • Stomach pain | • Heaviness in arms and legs |
| • Gas | • Memory loss |
| • Nausea and vomiting | • Unsteady walking |
| • Headache, including migraine | • Loss of appetite |
| • Leg cramps | • Indigestion |
| • Dizziness | • Numbness, tingling, pain, or burning of your skin |
| • Weakness | • Stomach bloating |
| • Vision problems | • Stomach pain not related to food |
| • Muscle cramps | • Menstrual changes |
| • Back pain | |
| • Constipation | |

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of ZAVESCA®. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Please see full Prescribing Information, including Patient Information, at www.zavesca.com.

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What to know about treatment with ZAVESCA® (miglustat)



ZAVESCA® may slow digestion of some carbohydrates

ZAVESCA® works by limiting the body's production and build-up of substances called glycosphingolipids (gli-coh-sfing-goh-lip-ids) in cells.^{1,2}

Just as it limits overproduction of these substances, ZAVESCA® may also slow down the digestion of certain carbohydrates, such as sugar and starch, which can cause gas, loose stools, or diarrhea.^{1,3}



GI symptoms can improve over time^{1,3}

In clinical trials, symptoms decreased over time with continued ZAVESCA® treatment.^{1,3}

You can also talk to your doctor about additional steps to help manage these side effects, including the tips throughout this guide.



Talk to your healthcare provider

Your healthcare team can provide tips to help manage certain side effects, including:



Take ZAVESCA® at the same time each day

The recommended dose is one 100 mg capsule three times a day at regular intervals. If a dose is missed, skip it and take the next ZAVESCA® capsule at the next scheduled time.¹



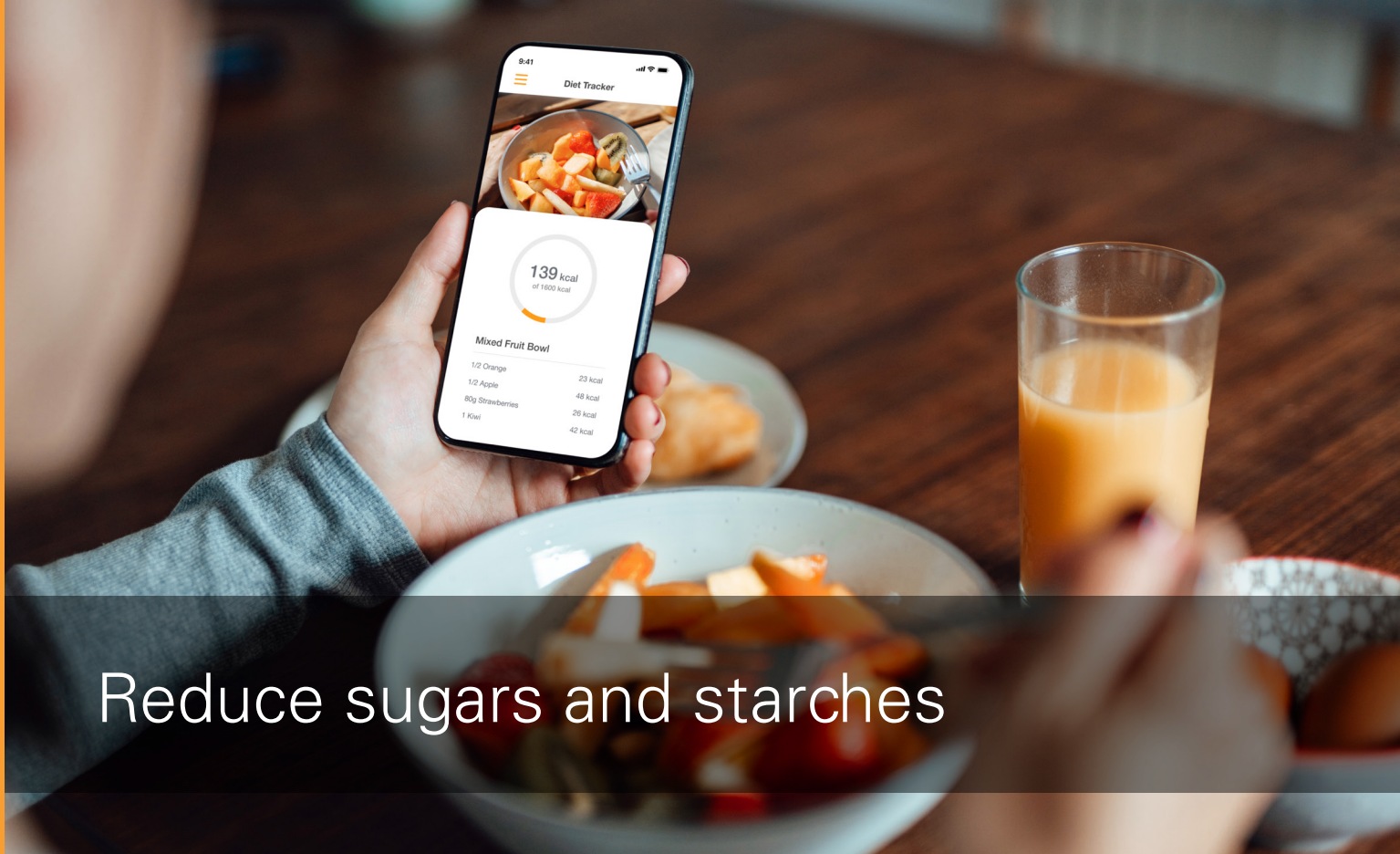
Consider an anti-diarrheal medication

Diarrhea is common with ZAVESCA® and sometimes can be serious. Your doctor may prescribe another medicine (anti-diarrheal) to treat diarrhea if it is a problem for you and may recommend changes to your diet, such as avoiding foods high in carbohydrates. Talk with your doctor about your diet if you have diarrhea.¹



Watch what carbohydrates you eat

Avoid having large portions of carbohydrates at one time.³ The remainder of this guide includes tips on dietary management and guidance on how to read food labels.^{1,3}



Reduce sugars and starches

If you experience diarrhea, loose stools, or gas while taking ZAVESCA® (miglustat), reducing the amount of certain kinds of sugars in your diet may help—**especially sugars known as disaccharides**, a type of carbohydrate that includes^{3,4}:

- ↓ **sucrose** (also known as table sugar)
- ↓ **lactose** (sugar that comes from milk, cheese, yogurts)
- ↓ **maltose** (your body naturally produces maltose as it digests starchy foods)

You don't need to cut these items out of your diet, but it is advisable to reduce your intake of foods high in starch and disaccharides as your body adjusts to ZAVESCA®.³

As your body adjusts to treatment with ZAVESCA®, you may be able to slowly bring back a normal diet.³

Talk to your doctor about when the time might be right for you.



Choose the right foods

In general, try to have your main meals consist of one-half fruits and vegetables, one-quarter meat or meat alternatives, and one-quarter grains⁵

See below for a list of dietary recommendations to help manage your sugar intake. Always consult your doctor or a dietitian before making any changes to your diet.

Fruits*



REDUCE (fruits high in sucrose)³: Eg, bananas, dates, peaches, apricots, pineapples, mangos, tangerines, dried fruits

Vegetables



AVOID high intake of carbohydrate-containing foods, including vegetables, such as carrots, beans, potatoes, peas, and corn, in one meal³

Grains/Cereals



ENJOY (in moderation)³: Foods like bread, breakfast cereals, pastries, rice, pasta, noodles
AVOID eating large portions of carbohydrates in a single meal³



Choose the right foods (continued)

Protein



ENJOY^{3,5}: Proteins like non-breaded meat (eg, beef, goat, lamb, pork, chicken, duck, turkey), fish (eg, black sea bass, salmon), tofu, eggs

Dairy



ENJOY³: Foods and drinks like lactose-free milk, unsweetened yogurt, soy-based products

REGULATE INTAKE³: Dairy products like whole milk, cream, yogurt, cream cheese

Beverages



RESTRICT INTAKE³: Naturally sweetened soft-drinks, sweetened commercial fruit juices, alcohol-containing drinks (eg, beer, wine)

Always consult your doctor before making any changes to your diet.

Check food labels

Check food labels to avoid foods with high amounts of starch and sugars with these tips:

Serving size

Avoid having too many servings of carbohydrates at one time.³

In the plain yogurt and fruit yogurt examples, the serving size is 3/4 cup

Carbohydrates and sugars

Take a look at the carbohydrate section and choose foods with less sugar.³

Try to reduce certain sugars (disaccharides) while taking ZAVESCA® (miglustat), including naturally occurring sugars (like those in fruit and milk) as well as added sugars.³

The plain yogurt has 5g of sugars, while the fruit yogurt has 15g of sugars.

Ingredients list

Look for added sweeteners to avoid, such as: **sucrose, dextrose, table sugar, syrups, honey, and sugars from concentrated fruit and vegetable juices.**⁶

Ingredients are listed in order of weight (from most to least), so you want to make sure that added sugars are not listed as one of the first few ingredients.⁷

Although no added sweeteners are listed in the ingredients for the plain yogurt, there are still 5g of sugars that are naturally occurring (from lactose in milk).⁴

Plain Yogurt⁶

Nutrition Facts	Amount/Serving % DV*		Amount/Serving % DV*	
	Total Fat 0g	0%	Total Carb. 5g	2%
3 servings per container	Sat. Fat 0g	0%	Dietary Fiber <1g	0%
	Trans Fat 0g		Total Sugars 5g	
Serving size 3/4 cup (170g)	Cholest. 10mg	3%	Incl. 0g Added Sugars	0%
	Sodium 65mg	3%	Protein 18g	
Calories 90 per serving 270 per container	Vitamin D 0mcg	0%	Iron 0mg	0%
	Calcium 200mg	15%	Potassium 260mg	4%

*The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

Ingredients

Cultured Pasteurized Grade A Fat Free Milk and Milk, Modified Tapioca Starch, Whey Protein Concentrate, Kosher Gelatin, Tricalcium Phosphate.

Fruit Yogurt⁶

Nutrition Facts	Amount/Serving % DV*		Amount/Serving % DV*	
	Total Fat 0g	0%	Total Carb. 15g	6%
5 servings per container	Sat. Fat 0g	0%	Dietary Fiber <1g	2%
	Trans Fat 0g		Total Sugars 15g	
Serving size 3/4 cup (170g)	Cholest. 10mg	3%	Incl. 10g Added Sugars	20%
	Sodium 65mg	3%	Protein 14g	
Calories 130 per serving 650 per container	Vitamin D 0mcg	0%	Iron 0mg	0%
	Calcium 170mg	15%	Potassium 220mg	4%

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Ingredients

Cultured Pasteurized Grade A Low Fat Milk, Sugar, Strawberries, Modified Corn Starch, **High Fructose Corn Syrup**, Nonfat Milk, Kosher Gelatin, Citric Acid, Tricalcium Phosphate, Natural Flavor, Pectin, Colored with Carmine, Vitamin A Acetate, Vitamin D3.

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References: 1. ZAVESCA® (miglustat) full prescribing information. Actelion Pharmaceuticals US, Inc. 2. Cox T, Lachmann R, Hollak C, et al. Novel oral treatment of Gaucher's disease with N-butyldeoxynojirimycin (OGT 918) to decrease substrate biosynthesis. *Lancet*. 2000;355(9214):1481-1485. doi:10.1016/S0140-6736(00)02161-9. 3. Belmatoug N, Burlina A, Giraldo P, et al. Gastrointestinal disturbances and their management in miglustat-treated patients. *J Inherit Metab Dis*. 2011;34(5):991-1001. doi:10.1007/s10545-011-9368-7. 4. Qi X, Tester RF. Lactose, Maltose, and Sucrose in Health and Disease. *Mol Nutr Food Res*. 2020;64(8):e1901082. 5. USDA. Dietary Guidelines for Americans 2020-2025 Make Every Bite Count with the Dietary Guidelines. Accessed May 15, 2025. https://www.dietaryguidelines.gov/sites/default/files/2021-03/Dietary_Guidelines_for_Americans-2020-2025.pdf. 6. US Food and Drug Administration. Added sugars: Now listed on the Nutrition Facts label. Accessed May 15, 2025. <https://www.fda.gov/media/135299/download>. 7. US Food and Drug Administration. A Food Labeling Guide. Guidance for industry. Accessed May 15, 2025. <https://www.fda.gov/media/81606/download>.

