


8 page brochure



**Healthy choices**

Please see important safety information throughout this brochure and on back cover and accompanying leaflet for handling information, including PPE information.

**zavitsca**  
insights

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**P.I.**

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# Healthy choices



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# 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

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

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 accompanying full Prescribing Information, including Patient Information.*

# choosing the right foods

## Reducing 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<sup>1</sup>—especially the sugars known as disaccharides, a type of carbohydrate that includes sucrose (also known as table sugar), lactose (milk sugar), and maltose.

The body naturally produces maltose as it digests starchy foods such as bread, breakfast cereals, legumes, potatoes, corn, rice, pasta, and other grains. You don't need to cut these items out of your diet, but it is advisable to decrease the amount of starchy foods you eat as your body adjusts to ZAVESCA. Also, try to avoid large servings of starchy foods at one time. Try to spread your intake over the course of a day.<sup>2</sup>

It's important to remember that different people react to ZAVESCA in different ways. As your body adjusts to treatment with ZAVESCA, you may be able to slowly bring certain foods back into your diet. Talk to your doctor about when the time might be right for you.

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**As recommended in the following pages, decrease your intake of foods high in starch and disaccharides (carbohydrates) and continue to enjoy foods that are low in starch and carbohydrates.<sup>3,4</sup>**

- Include moderate portions of starchy foods in your diet
- Try to have your main meals consist of one-half vegetables, one-quarter meat or meat alternatives, and one-quarter starchy foods
- Avoid having large portions at one time. Try to spread your intake of fruits, grains, and other starchy foods over the day
- Include at least 3 cups of appropriate dairy products or dairy substitutes daily; see the following pages for specific recommendations
- Eat at least 4 servings of allowed fruits every day, but avoid eating more than 1 serving at a time
- The nutrient labels on food packaging can tell you if a food contains high amounts of disaccharides. See the section titled "Understanding Food Labels" in this brochure for more information

# fruit

*At least 4 servings daily<sup>3</sup>*



## Enjoy fruits low in sucrose<sup>4,5</sup>:

|   |            |
|---|------------|
| olives                                    | grapefruit |
| avocados                                  | pears      |
| lemons, limes                             | apples     |
| berries<br>(raspberries,<br>strawberries) |            |



## Reduce fruits high in sucrose<sup>4,5</sup>:

|   |                |
|---|----------------|
| dates   | apricots       |
| dried fruit<br>(peaches, apricots)              | nectarines     |
| pineapple                                       | peaches        |
| tangerines,<br>clementines,<br>mandarin oranges | cantaloupe     |
|   | honeydew melon |

→ **Fruits contain sugar, so try eating only one serving at a time to see what may or may not bother you.**

These dietary recommendations are based on a 2,000 calorie daily diet. Actual caloric needs may vary by patient. Always consult your doctor before making any changes to your diet.<sup>3</sup>

<http://ndb.nal.usda.gov/ndb/search/list>

# vegetables

*Eat 4 to 5 servings daily<sup>3</sup>*



## Enjoy vegetables including<sup>5</sup>:

asparagus  
endive,  
lettuce  
broccoli  
cauliflower  
spinach

cabbage  
artichokes  
squash  
celery  
onions

peppers  
eggplant  
tomatoes



## Reduce these vegetables<sup>5</sup>:

### High in starch:

parsnips  
potatoes  
corn

### High in sugars (disaccharides):

beets  
green peas  
carrots  
sweet potatoes  
corn

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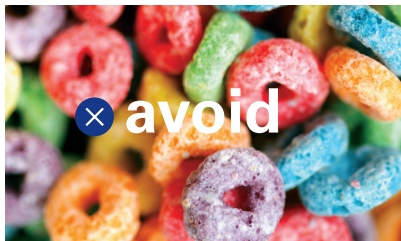
# grains and cereals

*Eat 6 servings a day<sup>3</sup>*



**low-sugar cereals**  
oatmeal, natural muesli (1/2 cup)  
whole grain breads  
plain or savory crackers or chips  
rice, pasta, noodles, couscous

**flours, polenta**  
unsweetened pastry



**sugary breakfast cereals**  
muesli bars and high-sugar  
breakfast bars  
fruit breads, white breads  
muffins, doughnuts  
desserts or sweets, such as candy  
bars, hard candy, and chocolate

**cakes, biscuits**  
sweet pastries,  
such as danishes

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# meats and meat alternatives

*Eat 4 to 5 times a week<sup>3</sup>*



**lean meats, including chicken, beef, pork, veal, and seafood**  
**legumes and lentils (adjust portions if necessary)**  
**protein shakes and protein bars with no added sugar or dairy**  
**eggs**  
**tofu**

# healthy fats

*Include daily<sup>3</sup>*



**nuts, seeds**  
**avocados**  
**margarines with no trans fats**  
**oils**

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# dairy foods

*At least 3 servings daily<sup>3</sup>*



**lactose-free milk**  
(liquid and powdered)

**soy milk** (but check for  
added sugar [sucrose]  
in flavored soy milk),  
soy shakes

**rice milk**

**lactose-free yogurt**

**soy yogurt** (natural,  
no added sugar)

**hard cheeses**



**milk**

**yogurt**

**sweetened milk**

**condensed milk**

**cottage cheese**

**cream cheese**

**cream**

**sour cream**

**milk-based desserts**

**ice cream**

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# enjoy occasionally

*In small portions*



**diet jelly**

**jam, peanut butter, honey,  
chocolate hazelnut spread  
(approximately 1 teaspoon)**

**some artificial sweeteners,  
including saccharin**

**fructose**

**sugar (up to 1 teaspoon  
added to tea, coffee, or  
plain unsweetened cereal)**

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# beverages

*In small portions*



**diet soft drinks**  
(artificially sweetened)

**tea and coffee** (but with only  
a little added milk or sugar)

**alcohol in limited amounts**  
(most types, except when mixed  
with juices or soft drinks, and  
cream-based liqueurs)

**soy shakes**

**almond shakes**



**sugar-sweetened drinks,**  
**fruit-flavored drinks, sports**  
**drinks, juices**

**liqueurs**

**chocolate or hot chocolate from**  
**dry powder**

**milk-based drinks**

**drinks with added sugar**  
(high-fructose corn syrup)

**orange juice**

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# understanding food labels

## One way to start managing your diet while on ZAVESCA® (miglustat) therapy

You've already learned that it's important to minimize the amount of food you eat containing high amounts of starch and sugars—specifically sucrose, maltose, and lactose—and to continue enjoying foods low in starch and carbohydrates. As described on the following pages, food labels can be your simple everyday guide to making good dietary choices.

Work with your doctor or a dietitian for help with choosing appropriate foods while you're on ZAVESCA therapy. You can also find information about the carbohydrate, fat, and protein content of individual foods at [www.nal.usda.gov](http://www.nal.usda.gov), <http://fnic.nal.usda.gov>, and <http://nutritiondata.self.com>.

## What the label says

On the right is an example of a food label.

Four sections of the label in particular are important to you while on therapy with ZAVESCA: serving size, carbohydrates, sugars, and ingredients list.

Serving size 1

Carbs 2

Sugars 3

Ingredients list 4

## Example label\*

| Nutrition Facts  |                      |
|--|----------------------|
| Serving Size   | 1 container          |
| Servings per container   | 1                    |
| Amount Per Serving   |                      |
| Calories 170   | Calories from Fat 15 |
| % Daily Value*   |                      |
| Total Fat 1.5g   | 3%                   |
| Saturated Fat 1g   | 5%                   |
| Trans Fat 0g   |                      |
| Cholesterol 10mg   | 3%                   |
| Sodium 80mg  | 3%                   |
| Total Carbohydrate 33g   | 11%                  |
| Dietary Fiber 0g   | 0%                   |
| Sugars 27g   |                      |
| Protein 5g   |                      |
| 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. |                      |

### 1 Serving size

The first place to start when you look at the Nutrition Facts label is the **serving size** and the number of servings in the package. Serving sizes are based on familiar units (such as cups or pieces), followed by an amount in metric units (such as milliliters or grams). In the fruit yogurt example to the right, a serving size is 1 container.

### 2 and 3 Carbohydrates and sugars

Because it is recommended that you reduce certain sugars (disaccharides) while taking ZAVESCA® (miglustat), you should look at sugars listed under the carbohydrate section of the Nutrition Facts label. These include naturally occurring sugars (like those in fruit and milk) as well as those added to a food or drink.\*

The example for 1 serving of the plain yogurt has 12g of sugars, while the fruit yogurt has 27g of sugars.

\*You can check the ingredients list for sugars that are not natural and have been added.

### 4 Ingredients list

Compare the **ingredients lists** for the two yogurts. Ingredients are listed in order of weight (from most to least). Make sure that **added sugars** are **not** listed as one of the **first few ingredients**. Other names for added sugars include corn syrup, high-fructose corn syrup, fruit juice concentrate, maltose, dextrose, sucrose, honey, and maple syrup.

You may notice that even though no added sugars or sweeteners are in the list of ingredients for the plain yogurt, the Nutrition Facts label shows 12g of sugars. This is because there are no **added** sugars in plain yogurt, only naturally occurring sugars (lactose in the milk).

## Plain Yogurt<sup>6</sup>

| Nutrition Facts   |                      |
|---|----------------------|
| Serving Size  | 8 oz                 |
| Servings per container  | 4                    |
| Amount Per Serving  |                      |
| Calories 140  | Calories from Fat 30 |
| % Daily Value*  |                      |
| Total Fat 3.5g  | 5%                   |
| Saturated Fat 2g  | 10%                  |
| Trans Fat 0g  |                      |
| Cholesterol 15mg  | 5%                   |
| Sodium 135mg  | 6%                   |
| Total Carbohydrate 17g  | 6%                   |
| Dietary Fiber 0g  | 0%                   |
| Sugars 12g  |                      |
| Protein 9g  |                      |
| Ingredients   |                      |
| Cultured Pasteurized Grade A Fat Free Milk and Milk, Modified Tapioca Starch, Whey Protein Concentrate, Kosher Gelatin, Tricalcium Phosphate. |                      |

## Fruit Yogurt<sup>6</sup>

| Nutrition Facts  |                      |
|--|----------------------|
| Serving Size   | 1 container          |
| Servings per container   | 1                    |
| Amount Per Serving   |                      |
| Calories 170   | Calories from Fat 15 |
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| Total Fat 1.5g   | 3%                   |
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| Sugars 27g   |                      |
| Protein 5g   |                      |
| Ingredients  |                      |
| Cultured Pasteurized Grade A Low Fat Milk, <b>Sugar</b> , Strawberries, Modified Corn Starch, <b>High Fructose Corn Syrup</b> , Nonfat Milk, Kosher Gelatin, Citric Acid, Tricalcium Phosphate, Natural Flavor, Pectin, Colored with Carmine, Vitamin A Acetate, Vitamin D3. |                      |

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### ZAVESCA may cause serious side effects including:

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

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.

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[www.actelion.com](http://www.actelion.com)



[www.zavesca.com](http://www.zavesca.com)

**References:** **1.** ZAVESCA® (miglustat) full prescribing information. Actelion Pharmaceuticals US, Inc. February 2014. **2.** Déchelotte P. Gastrointestinal and nutritional adverse effects of ZAVESCA (miglustat). Expert report; 2003. **3.** Dietary guidelines for Americans 2010. US Department of Agriculture. <http://www.cnpp.usda.gov/Publications/DietaryGuidelines/2010/PolicyDoc/PolicyDoc.pdf>. Accessed March 23, 2014. **4.** Belmatoug N, Burlina A, Giraldo P, et al. Gastrointestinal disturbances and their management in miglustat-treated patients. *J Inherit Metab Dis*. 2011;34:991-1001. **5.** US Department of Agriculture. National Nutrient Database for Standard Reference: Release 26. <http://ndb.nal.usda.gov/ndb/search/list>. Accessed March 23, 2014. **6.** US Food and Drug Administration. How to Understand and Use the Nutrition Facts Label. <http://www.fda.gov/food/ingredientspackaginglabeling/labelingnutrition/ucm274593.htm>. Accessed May 13, 2014.

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