

## **PATIENT MEDICATION INFORMATION**

### **READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE**

**P<sup>r</sup>VELTASSA<sup>®</sup>**

#### **patiromer powder for oral suspension**

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

#### **What is VELTASSA used for?**

VELTASSA is used to treat adults with high amounts of potassium in the blood. VELTASSA is only for use in patients with chronic kidney disease, except for end stage kidney disease.

#### **How does VELTASSA work?**

VELTASSA attaches to potassium in the intestine, so less potassium is absorbed into your blood. VELTASSA starts working within about 4 to 7 hours.

#### **What are the ingredients in VELTASSA?**

Medicinal ingredients: patiromer (as patiromer sorbitex calcium). This medicinal ingredient contains sorbitol and calcium. The sorbitol content is about 4 g (10.4 kcal) per 8.4 g of patiromer.

Non-medicinal ingredients: xanthan gum

#### **VELTASSA comes in the following dosage forms:**

Powder for oral suspension in sachets containing 8.4 g, 16.8 g, or 25.2 g patiromer (as patiromer sorbitex calcium).

#### **Do not use VELTASSA if:**

- you are allergic to patiromer or any other ingredients in VELTASSA.
- you have fructose intolerance because VELTASSA contains sorbitol.

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

- have problems swallowing.
- have severe stomach or bowel problems.
- had major surgery on your stomach or bowel.
- are pregnant or nursing, or think you may be pregnant or are planning to have a baby. It is not known if VELTASSA may be harmful to the fetus while you are pregnant or to your nursing baby.
- know you have a high level of calcium in your blood or you are taking calcium supplements.

**Other warnings you should know about:**

- Low blood magnesium can occur when taking VELTASSA. Your healthcare professional will check your magnesium level during at least the first month of treatment with VELTASSA and may prescribe a magnesium supplement.
- Your healthcare professional may monitor your potassium levels while you are taking VELTASSA. If your potassium levels drop too low, your dose of VELTASSA may be lowered or you may be told to stop taking VELTASSA.
- Do not stop taking VELTASSA without your healthcare professional's approval, as your potassium blood level may increase.

**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 VELTASSA:**

- telmisartan, bisoprolol, carvedilol, nebivolol (used to treat high blood pressure and certain heart conditions)
- ciprofloxacin (used to treat bacterial infections)
- levothyroxine (used to treat an underactive thyroid gland)
- metformin (used to treat diabetes)
- mycophenolate mofetil (used to suppress the immune system)
- quinidine (used to treat abnormal heartbeats)
- thiamine (vitamin B1)

Tell your healthcare professional if you take other oral medicines (taken by mouth). They will tell you how to take them during your treatment with VELTASSA. Some oral medicines should be taken at least 3 hours before or after you take VELTASSA. Your healthcare professional will tell you if this is necessary with the oral medicines you currently take.

**How to take VELTASSA:**

Always take this medicine exactly as your healthcare professional has told you. Check with your healthcare professional if you are not sure.

Mix VELTASSA with water or other liquids or soft foods listed further below. Stir until it is thoroughly mixed, as follows:

- Prepare about 40 mL (3 tablespoons) of water in a glass.
- Add the required number of VELTASSA sachets and stir.
- Add about 40 mL (3 tablespoons) of additional water and stir thoroughly. The powder does not dissolve but forms a suspension.
- You may add more water to the mixture to help you swallow the medicine.
- Drink the mixture within 1 hour after preparation and keep the mixture at room temperature. If powder remains in the glass after drinking, add more water, stir and drink immediately. You may need to do this again to make sure that you have taken all the powder.

You can use the following liquids or soft foods instead of water: apple juice, cranberry juice, pineapple juice, orange juice, grape juice, pear juice, apricot nectar, peach nectar, yogurt, milk, thickener (for example: cornstarch) in liquid or soft food, apple sauce, vanilla and chocolate pudding. Other liquids or soft foods cannot be used as they may contain high amounts of potassium. Remember to consider the potassium content of these liquids or soft foods shown

above when preparing VELTASSA.

Take the prepared VELTASSA suspension preferably at the same time each day, with or without food. Never heat VELTASSA or add it to hot foods or liquids.

Do not take VELTASSA as a dry powder.

**Usual dose:**

- Prepare Starting dose: 8.4 g patiromer (the content of one 8.4 g sachet) once daily
- Maximum dose: 25.2 g patiromer once daily

Your healthcare professional may adjust the dose depending on the potassium level in your blood.

Take VELTASSA at least 3 hours before or after other medicines taken by mouth unless your healthcare professional gives you different advice.

**Overdose:**

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

**Missed Dose:**

If you missed a dose of VELTASSA, take it as soon as you remember on the same day. But if it is almost time for your next dose, skip the missed dose and continue with your next scheduled dose. Go back to the regular dosing schedule. Do not take two doses at the same time. If you miss more than one dose, contact your healthcare professional.

**What are possible side effects from using VELTASSA?**

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

Most of the side effects with VELTASSA occur within the first 4 weeks of treatment.

- Common side effects (up to 1 in 10 people) include constipation, diarrhea, abdominal pain, low blood levels of potassium or magnesium and gas.
- Uncommon side effects (up to 1 in 100 people) include the following:
  - Stomach bloating, indigestion, upper abdomen discomfort, acid reflux, nausea and vomiting.
  - Allergic reactions such as swelling.
  - Anorexia.
  - Muscle cramping.
  - Altered sense of food taste.
  - Skin itching.
  - Low blood levels of iron or phosphorus.
  - Low blood pressure.

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/adverse-reaction-reporting.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 VELTASSA in the refrigerator (2°C - 8°C), unless the healthcare professional tells you to store it at room temperature (15°C - 25°C).
- Do not use VELTASSA after the discard date written on the carton by the healthcare professional. Consult your healthcare professional if no discard date was written on the carton, as this date typically occurs sooner than the expiry date.
- Do not expose VELTASSA to heat above 40°C.
- Keep out of reach and sight of children.
- Do not throw away any medicines via wastewater or household waste. Ask your healthcare professional how to throw away medicines you no longer use. These measures will help protect the environment.

### **If you want more information about VELTASSA:**

- 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 distributor's website ([www.otsukacanada.com](http://www.otsukacanada.com)), or by calling 1-877-341-9245.

This leaflet was prepared by Vifor Fresenius Medical Care Renal Pharma Ltd.

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