

## Package leaflet: Information for the patient

**Veltassa 8.4 g powder for oral suspension**  
**Veltassa 16.8 g powder for oral suspension**  
**Veltassa 25.2 g powder for oral suspension**  
patiromer (as patiromer sorbitex calcium)

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

### What is in this leaflet

1. What Veltassa is and what it is used for
2. What you need to know before you take Veltassa
3. How to take Veltassa
4. Possible side effects
5. How to store Veltassa
6. Contents of the pack and other information

#### 1. What Veltassa is and what it is used for

Veltassa is a medicine that contains the active substance patiromer.

Veltassa is used to treat adults with high levels of potassium in their blood.

Too much potassium in the blood can affect how your nerves control your muscles. This can lead to weakness or even paralysis. High potassium levels can also result in an abnormal heartbeat, which can cause serious effects on your heart rhythm.

Veltassa works by attaching to potassium in your gut. This prevents potassium from entering your bloodstream and lowers potassium levels in your blood back to normal.

#### 2. What you need to know before you take Veltassa

##### Do not take Veltassa

- if you are allergic to patiromer or any of the other ingredients of this medicine (listed in section 6).

##### Warnings and precautions

Talk to your doctor or pharmacist before taking Veltassa if you have:

- problems swallowing
- severe stomach or bowel problems
- had major surgery on your stomach or bowel.

Low blood magnesium can occur when taking Veltassa. Your doctor will check the magnesium level during treatment with Veltassa for at least 1 month and may prescribe a magnesium supplement if required.

### **Children and adolescents**

Do not give Veltassa to children under 18 years, as it has not been studied in this age group.

### **Other medicines and Veltassa**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Veltassa may affect certain medicines if they are taken by mouth and at the same time, such as:

- ciprofloxacin: a medicine to treat bacterial infections
- levothyroxine: a medicine to treat thyroid hormone deficiency
- metformin: a medicine to treat diabetes
- mycophenolate mofetil: a medicine to prevent your body rejecting a transplanted organ
- quinidine: a medicine to treat irregular heart rhythm
- telmisartan, bisoprolol, carvedilol, nebivolol: medicines to treat high blood pressure and for heart problems.

Unless your doctor or pharmacist does not give you different instruction as there are other medicines which are not affected by Veltassa, take all medicines taken by mouth at least 3 hours before or after you take Veltassa. Ask your doctor or pharmacist if you are not sure.

### **Pregnancy and breast feeding**

If you are pregnant or breast feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Use Veltassa during pregnancy and breast feeding only if your doctor considers it necessary.

### **Driving and using machines**

Veltassa has no or negligible influence on your ability to drive and use machines.

### **Veltassa contains sorbitol**

The sorbitol content is approximately 4 g (10.4 kcal) per 8.4 g of patiomer. Sorbitol is a source of fructose. If your doctor has told you that you have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you take or receive this medicine.

### **Veltassa contains calcium**

If your doctor has told you to limit calcium in your diet, talk to your doctor before you take or receive this medicine.

## **3. How to take Veltassa**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

- starting dose: 8.4 g patiomer (the content of one 8.4 g sachet) once daily
- maximum dose: 25.2 g patiomer (the content of one 25.2 g sachet) once daily

Your doctor 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 doctor or pharmacist gives you different advice.

### **Method of administration**

Mix Veltassa with the liquids or soft foods listed below and stir until it is thoroughly mixed, as follows:

- Prepare about 40 mL (3 tablespoons) of the liquid or soft food in a glass/bowl.
- Add the required number of Veltassa sachets and stir.
- Add about 40 mL (3 tablespoons) of additional liquid or soft food and stir thoroughly. The powder does not dissolve but forms a suspension, which might feel grainy.
- You may add more liquid or soft food to the mixture to help you swallow the medicine.
- Drink or eat the mixture within 1 hour after preparation. If powder remains in the glass/bowl after drinking/eating, add more liquid or soft food, stir and drink/eat immediately. You may need to do this again to make sure that you have taken all the powder.

You can use water or the following liquids or soft foods to prepare the mixture by following the same steps as described above: apple juice, cranberry juice, pineapple juice, orange juice, grape juice, pear juice, apricot nectar, peach nectar, yoghurt, milk, thickener (for example: cornstarch), apple sauce, vanilla and chocolate pudding.

When using such liquids and soft foods, follow your dietary recommendations on potassium intake. Check with your doctor or pharmacist if you are not sure.

You should drink only moderate amounts (less than 400 mL per day) of cranberry juice as it can affect other medicines.

Take the prepared Veltassa suspension with or without food, preferably at the same time each day. Never heat Veltassa or add it to heated foods or liquids. Do not take Veltassa as a dry powder.

### **If you take more Veltassa than you should**

Stop taking Veltassa and talk to your doctor or pharmacist immediately.

### **If you forget to take Veltassa**

If you have missed a dose, take it as soon as possible on the same day. Do not take a double dose to make up for a forgotten dose. If you miss more than one dose, contact your doctor.

### **If you stop taking Veltassa**

Do not stop taking the medicine without your doctor's approval, as your potassium blood level may increase.

## **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects have been reported:

**Common**, may affect up to 1 in 10 people:

- constipation
- diarrhoea
- abdominal pain
- wind
- low blood magnesium seen in tests

**Uncommon**, may affect up to 1 in 100 people:

- nausea
- vomiting

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

Yellow Card Scheme

Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store

### **5. How to store Veltassa**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton or sachet after “EXP”. The expiry date refers to the last day of that month.

Store and transport refrigerated (2°C – 8°C).

Once you have received Veltassa, it can be stored below 25°C for up to 6 months.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

### **6. Contents of the pack and other information**

#### **What Veltassa contains**

The active substance is patiromer (as patiromer sorbitex calcium).

- Veltassa 8.4 g powder for oral suspension: each sachet contains 8.4 g of patiromer
- Veltassa 16.8 g powder for oral suspension: each sachet contains 16.8 g of patiromer.
- Veltassa 25.2 g powder for oral suspension: each sachet contains 25.2 g of patiromer.

The other ingredient is xanthan gum.

#### **What Veltassa looks like and contents of the pack**

The powder for oral suspension is off white to light brown, with occasional white particles.

Veltassa is available in packs containing 30, 60 or 90 sachets.

Not all pack sizes may be marketed.

#### **Marketing Authorisation Holder**

Vifor Fresenius Medical Care Renal Pharma France  
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Tour Franklin La Défense 8  
92042 Paris La Défense Cedex  
France

#### **Manufacturer**

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For any information about this medicine, please contact the Marketing Authorisation Holder.

**This leaflet was last revised in  
September 2023**