PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Veltassa 8.4 g powder for oral suspension.
Veltassa 16.8 g powder for oral suspension.

Each sachet contains 8.4 g of patiromer (as patiromer sorbitex calcium).
Each sachet contains 16.8 g of patiromer (as patiromer sorbitex calcium).

For a list of inactive ingredients in the preparation – see section 6.

Read the entire leaflet carefully before using the medicine.
This leaflet contains concise information about the medicine.
If you have any other questions, refer to the doctor or the pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

1. What is the medicine intended for?

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

Too much potassium in the blood can affect the way your nerves control your muscles. This can lead to weakness or even paralysis. High potassium levels can result in abnormal heartbeat, which can severely affect your heart rhythm.

Veltassa binds to potassium in your gut. This way Veltassa prevents potassium from reaching the blood and lowers potassium blood levels back to normal.

Therapeutic class: Medicines for treatment of hyperkalemia and hyperphosphatemia.

2. Before using the medicine:

Do not use this medicine if:

- You are sensitive (allergic) to patiromer or any other ingredient of this medicine (see section 6).

Special warnings regarding the use of the medicine:

Before treatment with Veltassa, inform the doctor if:
- You have problems swallowing.
- You have severe stomach or bowel problems.
- You have had major surgery in your stomach or bowel.

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

Tests and follow-up
Taking Veltassa may lead to low magnesium levels in the blood. Your doctor will check your magnesium levels at the beginning of treatment, within at least one month after the beginning of treatment and according to clinical need.

Drug interactions:
If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist. Especially if you are taking:

- Ciprofloxacin: a medicine for treatment of bacterial infections.
- Levothyroxine: a medicine for treatment of thyroid hormone deficiency.
- Metformin: a medicine for treatment of diabetes.
- Mycophenolate mofetil: a medicine used to prevent rejection of transplanted organs.
- Quinidine: a medicine for treatment of irregular heartbeat.
- Telmisartan, bisoprolol, carvedilol, nebivolol: medicines for treatment of high blood pressure and heart problems.

Use of the medicine and food
Take the prepared Veltassa suspension with or without food.

Pregnancy and breastfeeding
If you are pregnant or breastfeeding, think you are pregnant or are planning to become pregnant, consult with your doctor or pharmacist before taking this medicine.

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

Driving and operating machinery
Veltassa has no effect or a negligible effect on your ability to drive and operate machinery.

Important information regarding some of the ingredients of the medicine
Veltassa contains sorbitol. If you have been told by your doctor that you have an intolerance to certain sugars, contact your doctor before taking this medicinal preparation. The sorbitol content is approximately 4 g (10.4 kcal) per 8.4 g of patiromer.
Veltassa contains calcium. If you have been told by your doctor to limit your calcium intake, consult the doctor before taking this medical preparation.

3. How should you use the medicine?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the preparation.
The dosage and treatment regimen will be determined by the doctor only.

The generally accepted dosage is:
- Starting dose: 8.4 g patiromer (the content of one 8.4 g sachet) once daily.
- Maximum dose: 25.2 g patiromer (the content of one 8.4 g sachet and one 16.8 g sachet) once daily.

Your doctor may adjust the dosage according to the potassium level in your blood.

Take Veltassa at least 3 hours before or after taking other oral medicines unless your doctor or pharmacist has instructed you otherwise.

Do not exceed the recommended dose.

<u>Method of administration</u>
Mix Veltassa with the liquids and soft foods listed below and stir well 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 well. The powder does not dissolve but forms a suspension, which may be granular.
- You may add more liquid or soft food to the mixture to help you swallow the medicine.
- Drink or eat the mixture within one hour of 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 in the manner described above: apple juice, cranberry juice, pineapple juice, orange juice, grape juice, pear juice, apricot nectar, peach nectar, yoghurt, milk, thickener (e.g., corn starch), apple sauce, vanilla or chocolate pudding.
When using such liquids or 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 every day. Never heat Veltassa or add it to heated foods or drinks. Do not take Veltassa as a dry powder.

If you accidentally took a higher dosage of the medicine
If you accidentally took a higher dose or if a child accidentally swallowed the medicine, stop taking Veltassa and immediately refer to a doctor or a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine
If you forgot to take one dose, take it as soon as possible on the same day. Do not take a double dose in order to compensate for the dose that you forgot to take. If you forgot to take more than one dose, contact your doctor.

Follow the treatment as recommended by the doctor.

If you stop taking the medicine
Do not stop taking the medicine without a doctor's approval, as your potassium blood levels may rise.

Do not take medicines in the dark! Check the label and the dose <u>every time</u> you take the medicine. Wear glasses if you need them.
If you have any other questions regarding the use of the medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, the use of Veltassa may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Common side effects - side effects that occur in 1-10 out of 100 users:
- Constipation.
- Diarrhea.
- Abdominal pain.
- Flatulence.

- Low levels of magnesium in the blood, which are observed in tests.

Uncommon side effects - side effects that occur in 1-10 out of 1,000 users:
- Nausea.
- Vomiting.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects
Side effects may be reported to the Ministry of Health by clicking on the link "report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: https://sideeffects.health.gov.il/

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date appearing on the carton package or the sachet after the word EXP. The expiry date refers to the last day of that month.
- **Storage conditions:** Store and transport refrigerated (2°C – 8°C).
  Veltassa may be stored below 25°C for up to 6 months.

6. Additional information:

- In addition to the active ingredient, the medicine also contains:
  xanthan gum

- What does the medicine look like and what are the contents of the package:
  The powder for oral suspension is between off white (cream) and light brown.
  Veltassa is available in packs containing 30 sachets.

- Marketing authorization holder and address: CTS Ltd., 4 Haharash St., Hod Hasharon, Israel

- Name and address of the manufacturer:
  Vifor Fresenius Medical Care Renal Pharma Ltd., Switzerland.
  Rechenstrasse 37 CH-9017 St. Gallen, Switzerland.

- Registration numbers of the medicines in the national drug registry of the Ministry of Health:
  Veltassa 8.4 g – 161-52-35491
  Veltassa 16.8 g – 161-53-35492

This leaflet was revised in 12/2022 in accordance with the Ministry of Health guidelines.