Package leaflet: Information for the patient

Veltassa 1 g powder for oral suspension
Veltassa 8.4 g powder for oral suspension
Veltassa 16.8 g powder for oral suspension
patiromer (as patiromer sorbitex calcium)

Read all of this leaflet carefully before you or your child 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 or your child 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 or your child 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

Veltassa is a medicine that contains the active substance patiromer.

This medicine is used to treat adults and adolescents aged 12 to 17 years with high levels of potassium in their blood.

Too much potassium in the blood can affect how nerves control 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 or your child's heart rhythm.

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

2. What you need to know before you take Veltassa

Do not take Veltassa
- if you or your child 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 using Veltassa if you or your child have:
- problems swallowing - If you cannot swallow this medication, it won’t work.
- severe stomach or bowel problems - This medicine may cause constipation or diarrhoea in some patients.
- had major surgery on your stomach or bowel - This medicine works while passing through the bowel, so major surgery in this area may impact the effect of this medicine.

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

Children and adolescents
Do not give this medicine to children under 12 years, as it has not been studied in this age group.

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

This medicine may reduce absorption or interact with 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.

Use all medicines taken by mouth at least 3 hours before or after you use Veltassa. Some medicines are not affected by Veltassa, so your doctor or pharmacist may give you a different instruction depending on the medicines you or your child are taking. 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 this medicine during pregnancy and breast feeding only if your doctor considers it necessary.

Driving and using machines
This medicine has no or negligible influence on the ability to drive and use machines.

Veltassa contains sorbitol
The sorbitol content is approximately 4 g (10.4kcal) per 8.4 g of patiromer and approximately 0.5 g (1.2 kcal) per 1 g of patiromer. Sorbitol is a source of fructose. If your doctor has told you that you or your child have an intolerance to some sugars or if you or your child 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 using this medicine. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

Veltassa contains calcium
If your doctor has told you to limit calcium in your or your child's diet, talk to your doctor before you use this medicine. Your doctor will check the calcium level during treatment with this medicine for at least 1 month.

3. How to take Veltassa

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

This medicine is administered once daily. The recommended starting dose of Veltassa varies with age. Multiple sachets may be used to achieve the desired dose. Your doctor may adjust the daily dose depending on the potassium level in your or your child's blood, up to a maximum dose of 25.2 g daily.

Adults
Starting dose: 8.4 g patiromer (the content of one 8.4 g sachet) once daily.

Adolescents aged 12 to 17 years
Starting dose: 4 g patiromer (the content of four 1 g sachets) once daily. Switch to 8.4 g patiromer sachets if doses above 7 g are needed.

Your doctor will decide on the duration of the treatment based on the potassium level in blood.

Use this medicine at least 3 hours before or after other medicines taken by mouth unless your doctor or pharmacist gives you different advice.

Method of administration
Before you take this medicine, it needs to be mixed with water as described below. The volume of water depends on your dose:
- 1 g patiromer: 10 mL (2 teaspoons)
- 2 g patiromer: 20 mL (4 teaspoons)
- 3 g patiromer: 30 mL (6 teaspoons)

4 g patiromer:
- 40 mL (3 tablespoons)
- Above 4 g patiromer: 80 mL (6 tablespoons)

Prepare the mixture according to the following steps:
- Pour half of the water in a glass.
- add the required number of Veltassa sachets and stir.
- Add the remaining half of the water and stir thoroughly. The powder does not dissolve but forms a suspension, which might feel grainy.
- You may add more water to the mixture to help you swallow the medicine. Please note that with larger volumes the powder might settle down more quickly.
- Drink the mixture within 1 hour after preparation. 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.

If you like, you can use the following liquids or soft foods instead of water 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 or your child's 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.

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

If you use a nasogastric tube or percutaneous endoscopic gastrostomy tube, follow the steps described above to prepare the suspension for oral administration. For doses up to 8.4 g patiromer, use the volume as described above. For doses above 8.4 g and up to16.8 g patiromer use a total volume of 160

mL (12 tablespoons) and for doses above 16.8 g and up to 25.2 g patiromer use a total volume of 240 mL (18 tablespoons). These volumes ensure that the suspension readily flows through the tubes.

Tubes made from polyurethane, silicone, and polyvinyl chloride may be used. The recommended diameter of tubes is 2.17 mm (6.5 Fr) or larger. After administration of the suspension, the tube should be flushed with water. Follow tube manufacturer's instructions.

If you take more Veltassa than you should
Stop using this medicine and talk to your doctor or pharmacist immediately.

If you forget to take Veltassa
If you or your child 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 using this medicine without your doctor's approval, as the potassium blood level may increase.

4. Possible side effects

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

Stop taking the medicine and seek urgent medical advice if you notice any of the following side effects:
Not known, frequency cannot be estimated from the available data:
allergic reactions: symptoms include rash, hives, swelling of the lips, tongue or throat.

The following other side effects have been reported:
Common, may affect up to 1 in 10 people:
- constipation
- diarrhoea
- abdominal pain
- nausea
- wind
- low blood magnesium seen in tests

Uncommon, may affect up to 1 in 100 people:
- vomiting

Constipation, diarrhoea, and wind have also been reported in children and adolescents 6 to 17 years of age.

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: https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store.
By reporting side effects, you can help provide more information on the safety of this medicine.

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 this medicine, 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 1 g powder for oral suspension: each sachet contains 1 g of patiromer.
- 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.

The other ingredient is xanthan gum (see section 2 for information about sorbitol).

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 1 g is available in packs containing 60 sachets.

Veltassa 8.4 g and 16.8 g are 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
100–101 Terrasse Boieldieu
Tour Franklin La Défense 8
92042 Paris La Défense Cedex
France

Manufacturer
Vifor France
100–101 Terrasse Boieldieu
Tour Franklin La Défense 8
92042 Paris La Défense Cedex
France

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

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