

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Veltassa?

Veltassa contains the active ingredient patiromer (as sorbitex calcium). Veltassa is used to help remove excessive amounts of potassium from the blood (hyperkalaemia). For more information, see Section 1. Why am I using Veltassa? in the full CMI.

2. What should I know before I use Veltassa?

Do not use if you have ever had an allergic reaction to Veltassa or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section 2. What should I know before I use Veltassa? in the full CMI.

3. What if I am taking other medicines?

Veltassa may interfere with the absorption of some medicines and reduce their activity if taken together.

A list of these medicines is in Section 3. What if I am taking other medicines? In the full CMI.

4. How do I use Veltassa?

- The recommended dose is: starting dose: 8.4 g Veltassa (1x8.4 g sachet) once daily; maximum dose: 25.2 g Veltassa (3x8.4 g sachets) once daily. Your doctor may adjust the dose during the treatment course depending on the potassium level in your blood.
- Mix Veltassa with the recommended liquids or soft foods and stir until it is thoroughly mixed.
- Take the prepared Veltassa suspension with or without food and preferably at the same time each day.
- In general, Veltassa should be separated by 3 hours from other oral medicines.

More instructions can be found in Section 4. How do I use Veltassa? In the full CMI.

5. What should I know while using Veltassa?

| Things you should do | Remind any doctor, dentist or pharmacist you visit that you are using Veltassa. |
|-----------------------------|---|
| Things you should not do | Never heat Veltassa or add it to heated foods or liquids. Do not take Veltassa in its dry form. Do not stop taking the medicine without your doctor's approval, as your potassium blood level may increase. |
| Driving or using machines | Be careful before you drive or use any machines or tools until you know how Veltassa affects you. |
| Drinking alcohol | The effect of alcohol on Veltassa has not been formally studied, however, no effect is expected |
| Looking after your medicine | It is recommended to store Veltassa in the refrigerator (at 2°C to 8°C) (Do not store in the freezer). Veltassa may be stored below 25°C for up to 6 months. Protect from heat. |

For more information, see Section 5. What should I know while using Veltassa? In the full CMI.

6. Are there any side effects?

Common side effects include: constipation, diarrhoea, abdominal pain, wind. Low blood magnesium and/or potassium can occur when taking Veltassa. Uncommon side effects that may require medical attention include: nausea, vomiting, dizziness, fast or irregular heartbeats, also called palpitations.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? In the full CMI.

Veltassa

Active ingredient: patiromer (as sorbitex calcium)

Consumer Medicine Information (CMI)

This leaflet provides important information about using Veltassa. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Veltassa.

Where to find information in this leaflet:

- 1. Why am I using Veltassa?
- 2. What should I know before I use Veltassa?
- 3. What if I am taking other medicines?
- 4. How do I use Veltassa?
- 5. What should I know while using Veltassa?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using Veltassa?

Veltassa contains the active ingredient patiromer (as sorbitex calcium). Veltassa is used to help remove excessive amounts of potassium from the blood (hyperkalaemia). It works by binding extra potassium in your digestive tract. This increases the amount of potassium excreted and thus lowers potassium levels in your blood.

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

2. What should I know before I use Veltassa?

Warnings

Do not use Veltassa if:

- you are allergic to patiromer (as sorbitex calcium), or any of the ingredients listed at the end of this leaflet.
 Symptoms of an allergic reactions are shortness of breath, wheezing or difficulty breathing, swelling of the face, lips or tongue or other parts of the body, rash, itching, or hives on the skin.
- the packaging is damaged or shows signs of tampering.
- It is past the expiry date (EXP) printed on the pack
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions including severe stomach and/or bowel problems
- take any medicines for any other condition
- have problems swallowing
- had major surgery on your stomach and/or bowel
- have high calcium levels in your blood.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and

how to monitor for them. See additional information under Section <u>6</u>. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor can discuss with you the risks and benefits involved.

Use in children

- Do not give this medicine to a child under the age of 18 years.
- Safety and efficacy of Veltassa in children below the age of 18 years have not yet been established.
 Therefore, Veltassa is not recommended in this age group.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Take Veltassa at least 3 hours before or after taking any other medicine by mouth. Veltassa may affect other medicines taken by mouth if they are taken too close together. This can cause you to have too little of other medicines in your body which may affect the way your other medicines work. Separation is not needed for certain medicinal products. Check with your doctor or pharmacist to confirm which medicines are impacted.

Examples of medicines that Veltassa may affect if they are taken by mouth at the same time include:

- telmisartan: a medicine used to treat high blood pressure and heart failure
- bisoprolol, carvedilol, nebivolol: medications used to treat high blood pressure
- ciprofloxacin: a medicine to treat bacterial infections
- levothyroxine: a medicine to treat thyroid hormone deficiency
- metformin: a medicine to treat diabetes
- quinidine: a medicine to treat irregular heart rhythm.
- mycophenolate mofetil: a medication used to lower the body's natural immunity in patients who receive organ transplants
- thiamine: used to treat or prevent vitamin B1 deficiency

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Veltassa.

4. How do I use Veltassa?

How much to take

- The recommended starting dose is 8.4 g Veltassa sachet once daily
- The recommended maximum dose is 25.2 g Veltassa (3x8.4g sachets) once daily
- Your doctor may adjust the dose during the treatment course depending on the potassium level in your blood
- Follow the instructions provided and use Veltassa until your doctor tells you to stop.

When to take Veltassa

 The prepared Veltassa suspension should be taken with or without food, preferably at the same time each day.

How to take Veltassa

Mix Veltassa with water and stir to a suspension of uniform consistency, as follows:

- Measure 80 ml (1/3 cup) of water.
- Pour half of the water into a glass, then add Veltassa and stir.
- Add the remaining half of the water and stir thoroughly. The powder will not dissolve and the mixture will look cloudy.
- Add more water to the mixture as needed for desired consistency.
- Drink the mixture immediately. If powder remains in the glass after drinking, add more water, stir and drink immediately. Repeat as needed to ensure the entire dose is taken.

The following liquids or soft foods can be used 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, apple sauce, vanilla and chocolate pudding.

When using such liquids and soft foods, follow your dietary recommendations on potassium intake. Other liquids containing high levels of potassium cannot be used. Check with your doctor or pharmacist if you are not sure.

Take Veltassa at least 3 hours before or 3 hours after other medicines taken by mouth unless your doctor or pharmacist gives you different advice. See additional information under Section 3.What if I am taking other medicines?

Never heat Veltassa or add it to heated foods or liquids.

Do not take Veltassa in its dry form.

If you forget to take Veltassa

Veltassa should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as possible on the same day. If you missed a day, take the next Veltassa dose at the usual time.

Do not take a double dose to make up for the dose you missed.

• If you miss more than one dose, contact your doctor.

If you use too much Veltassa

If you think that you have used too much Veltassa, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Veltassa?

Things you should do

Remind any doctor, dentist or pharmacist you visit that you are using Veltassa.

Things you should not do

- Never heat Veltassa or add it to heated foods or liquids.
- Do not take Veltassa in its dry form.
- Do not stop taking the medicine without your doctor's approval, as your potassium blood level may increase.
- Do not use Veltassa after the expiry date.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Veltassa affects you.

Looking after your medicine

- It is recommended to store Veltassa in the refirgerator (at 2°C to 8°C) (Do not store in the freezer).
- Veltassa may be stored below 25°C for up to 6 months.
- Protect from heat.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

When to discard your medicine

Discard Veltassa 6 months after taking out of the refrigerator or after expiry date if stored in the refrigerator.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date. The expiry date refers to the last day of that month.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

| Less serious side effects | What to do |
|---|---|
| Gastrointestinal disorders: constipation diarrhoea abdominal pain wind Low blood magnesium and/or potassium can occur when taking Veltassa. Your doctor will check your magnesium and potassium levels during treatment with Veltassa and may prescribe a supplement if required. | Speak to your doctor if you have any of these less serious side effects and they worry you. |

Serious side effects

| Side effects that may require medical attention | What to do |
|---|--|
| nausea vomiting dizziness fast or irregular heartbeats, also called palpitations | Speak to your doctor if you have any of these uncommon side effects as they may require medical attention. |

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Veltassa contains

| Active ingredient | patiromer (as sorbitex calcium) | |
|------------------------|---|--|
| (main ingredient) | Each 8.4 g sachet contains 8.4 g of patiromer (as sorbitex calcium). Each 16.8 g sachet contains 16.8 g of patiromer (as sorbitex calcium). Each 25.2 g sachet contains 25.2 g of patiromer (as sorbitex calcium). | |
| Other ingredients | Xanthan gum | |
| (inactive ingredients) | | |
| Potential allergens | None | |
| | Does not contain lactose, gluten, starch, gelatin, nut allergens, vegetable oils, cereal, milk proteins, fish oil and/or its derivatives, egg and/or its derivates, dried fruits, fruit flavourings, fruit essences, materials of human or animal origin. | |

Do not take this medicine if you are allergic to any of these ingredients.

What Veltassa looks like

Veltassa sachets contain an off-white to light-brown powder, with occasional white particles.

Veltassa is available in packs containing 30 sachets.

Not all strengths may be marketed.

(8.4 g AUST R 281012

16.8 g AUST R 281014

25.2 g AUST R 281013)

Who distributes Veltassa

Distributed in Australia by:

CSL Seqirus 655 Elizabeth Street, Melbourne, VIC 3000

Australia

1800 642 865 (Within Australia)

Sponsor

Seqirus Pty Ltd 63 Poplar Rd, Parkville VIC 3052 Australia

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