Veltassa®

8.4 g, 16.8 g and 25.2 g powder for oral suspension

patiromer (as sorbitex calcium)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about VELTASSA. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist. All medicines have risks and benefits. Your doctor has weighed the risks of you being given VELTASSA against the expected

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

benefits it will have for you.

What VELTASSA is used for

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.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

Before you take VELTASSA

When you must not take it

Do not take VELTASSA if you have an allergy to patiromer sorbitex calcium or any of the ingredients listed at the end of this leaflet.

Some symptoms of an allergic reaction include:

- · 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

Do not take it after the expiry date (EXP) printed on the pack.

If you take it after the expiry date has passed, it may not work as well.

Do not take it if the packaging is damaged or shows signs of tampering.

If you are not sure whether you should take VELTASSA, talk to your doctor or pharmacist

Before you start to take VELTASSA

Tell your doctor or pharmacist if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- · problems swallowing
- · severe stomach and/or bowel problems
- had major surgery on your stomach and/or bowel
- high calcium levels in your blood

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.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

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

If you have not told your doctor about any of the above, tell him/her before you take VELTASSA.

Taking other medicines

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

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. Therefore, take Veltassa at least 3 hours before or after taking any other medicine by mouth.

Your doctor and pharmacist have more information on medicines to be careful with or avoid when taking VELTASSA.

How to take VELTASSA

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

How much to take

The recommended dose is:

- starting dose: 8.4 g patiromer once daily
- maximum dose: 25.2 g patiromer once daily

Your doctor may adjust the dose during the treatment course depending on the potassium level in your blood.

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.

Apple juice or cranberry juice can be used instead of water, if preferred. Other liquids containing high levels of potassium cannot be used.

Take the prepared VELTASSA suspension with or without food and preferably at the same time each day.

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

Do not take VELTASSA in its dry form.

If you forget to take it

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 it

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

If you take too much (overdose)

Stop taking VELTASSA and talk to your doctor or pharmacist immediately or telephone the Poisons Information Centre on 13 11 26, for advice if you take more VELTASSA than you should.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking VELTASSA.

Do not be alarmed by the following list of side effects, you may not experience any of them

Tell your doctor if you notice any of the following common side effects and they worry you:

- · 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.

The above list includes the more common side effects.

Tell your doctor as soon as possible if you notice any of the following:

- nausea
- vomiting
- · dizziness
- fast or irregular heartbeats, also called palpitations

The above list includes uncommon side effects that may require medical attention.

Tell your doctor if you notice anything that is making you feel generally unwell.

Other side effects not listed above are rare and may also occur in some people.

Storage

Store at 2-8°C in the refrigerator.

VELTASSA may be stored below 25°C for up to 6 months.

Protect from heat.

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.

Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills.

Keep VELTASSA out of the sight and reach of children.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it 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.

Ingredients

The active substance is patiromer sorbitex calcium.

- 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).

The other ingredient is xanthan gum.

Supplier

VELTASSA is supplied in Australia by:

Vifor Pharma Pty Ltd

Level 9, 140 William Street Melbourne VIC 3000 Australia

Tel: 1800 202 674

Australian registration number:

8.4 g AUST R 281012

16.8 g AUST R 281014

25.2 g AUST R 281013

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