NHS
Shropshire, Telford and Wrekin
Clinical Commissioning Group

The Shrewsbury and Telford Hospital NHS
NHS Trust

Prescribing information for patiromer (Veltassa®▼) for the treatment of chronic hyperkalaemia in adults

Licensed Indication

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Patiromer (Veltassa®) is indicated for the treatment of hyperkalaemia in adults.

NICE[1] support the use of patiromer (Veltassa®) under the following criteria:
It is recommended as an option for treating hyperkalaemia in adults only if used:

- for people with persistent hyperkalaemia and stages 3b to 5 chronic kidney disease or heart failure, if they:
  - have a confirmed serum potassium level of at least 6.0 mmol/litre and
  - are not taking, or are taking a reduced dosage of, a renin-angiotensin-aldosterone system (RAAS) inhibitor because of hyperkalaemia and
  - are not on dialysis.

NICE[1] has recommended to stop patiromer (Veltassa®) if RAAS inhibitors are no longer suitable.

Dosage and administration[2]

Patiromer (Veltassa®) is administered orally and should be taken with food. The recommended starting dose is 8.4g once daily and the maximum dose is 25.2 g. The dose can be increased or decreased after a minimum interval of 1 week based on serum potassium levels. The dose should be reduced or stopped if serum potassium is below the desired range.

Patiromer (Veltassa®) should be mixed with water and stirred to a suspension of uniform consistency, according to the following steps:

The complete dose should be poured into a glass containing approximately 40 mL of water, then stirred. Another approximately 40 mL of water should be added, and the suspension stirred again thoroughly. The powder will not dissolve. More water may be added to the mixture as needed for desired consistency.

The mixture should be taken within 1 hour of initial suspension. If powder remains in the glass after drinking, more water should be added and the suspension stirred and taken immediately. This may be repeated as needed to ensure the entire dose is administered.

Administration of patiromer (Veltassa®) should be separated by at least 3 hours from other oral medicinal products.

Apple juice or cranberry juice can be used instead of water to prepare the mixture. Other liquids should be avoided as they may contain high amounts of potassium.

Specialist responsibilities

- Discuss the benefits and side effects of treatment with the patient.
- Initiate and stabilise treatment with patiromer (Veltassa®) for 2-3 months. During this period, potassium levels must be within the normal range (3.5-5.3mmol/l) before transferring patient to primary care.
- Correct potassium and magnesium depletion before starting treatment and monitor plasma-potassium (as clinically indicated), including after changes are made to medicinal products that affect the serum potassium concentration (e.g. RAAS inhibitors or diuretics) and after the patiromer (Veltassa®) dose is titrated.
- Correct plasma-magnesium prior to initiating patiromer (Veltassa®) and continue to monitor for at least 1 month after initiation of treatment. Both levels must be in normal range (0.7-1.0 mml/l) before transferring patient to primary care.
- Monitor U+Es every 6-8 weeks and advise GP regarding any dose adjustments. If potassium levels fall outside the normal range, specialist will advise GP regarding any dose adjustments.
- Monitor patient after any adjustments made.
- Review patient every 4-6months.
- Communicate to the GP established regimen; follow up arrangements and when to refer back.
- Communicate promptly with the GP when treatment is changed.

- Have a mechanism in place to receive referral of a patient from the GP in the event of rare or severe side-effects.
- Discontinue treatment with patiromer (Veltassa®) if serum potassium is below the desired range.
- Ensure that clear backup arrangements exist for GPs to obtain advice and support
- Report adverse events to the MHRA (via Yellow Card) www.mhra.gov.uk/Safetyinformation/Reportingsafetyproblems/index.htm

Primary Care responsibilities

- Prescribe the patiromer (Veltassa®) at the dose recommended, from the agreed date.
- Adjust the dose as advised by the specialist. The responsibility for monitoring the response to the dose change lies within the specialist.
- Report to & seek advice from the specialist if GP has U+Es available prior to specialist review.
- Report to & seek advice from the specialist on any aspect of patient care of concern to the GP that may affect treatment.
- Seek immediate specialist advise and refer back to specialist if the patient's condition deteriorates or if the potassium level falls outside the normal range as indicated on a routine blood test. Immediate referral should be done by contacting the specialist via the number given below.
- Stop treatment on the advice of the specialist or immediately if an urgent need to stop treatment arises. GP should not stop treatment or adjust dose unless requested by the specialist.
- Report adverse events to the MHRA (via Yellow Card) www.mhra.gov.uk/Safetyinformation/Reportingsafetyproblems/index.htm

Communication

BACK-UP ADVICE AND SUPPORT

Contact details	Telephone No.	Email address:
Specialist: Dr S Ramadoss	PRH 01952 641222 via switch	
Hospital Pharmacy Dept:	RSH 01743 261000 ext 1174 PRH 01952 641222 ext 4360	
Other:		

Monitoring

Monitoring must be done by the specialist in secondary care unless the GP has U+Es available prior to specialist review. In this case, GP should report and seek advice from the specialist when required. Once treatment is started the specialist takes full responsibility for monitoring and dose adjustment – informing the GP of dose changes and monitoring of the blood potassium after any dose adjustments.

Serum potassium should be monitored when clinically indicated, including after changes are made to medicinal products that affect the serum potassium concentration (e.g. RAAS inhibitors or diuretics) and after the patiromer (Veltassa®) dose is titrated. Specialist nephrologists monitor all CKD and heart failure patient bloods for routine follow ups and will inform the GP if potassium level is outside of the normal range and advise about dose change or stopping treatment as necessary. Patients should be referred back to virtual renal outpatient appointment id serum potassium level is persistently high.

Contra-indications, Special warnings/precautions & adverse effects

Contra-indications:
Hypersensitivity to the active substance or the excipient - xanthan gum. Patiromer (Veltassa®) contains sorbitol as part of the counterion complex. Patients with rare hereditary problems of fructose intolerance should not take this medicine.

Special warnings/precautions:
Risk factors for hypercalcaemia (calcium partially released from counterion complex); severe gastro-intestinal disorders (ischaemia, necrosis, and intestinal perforation reported with other potassium binders).

When discontinuing patiromer (Veltassa®), serum potassium levels may rise, especially if RAAS inhibitor treatment is continued. Increases in serum potassium may occur as early as 2 days after the last patiromer (Veltassa®) dose.

Adverse Effects

The majority of the adverse reactions (ARs) reported from trials were gastrointestinal disorders, with the most frequently reported ARs being constipation (6.2%), diarrhoea (3%), abdominal pain (2.9%), flatulence (1.8%) and hypomagnesaemia (5.3%).

Drug Interactions

Concomitant administration of patiromer showed reduced bioavailability of ciprofloxacin, levothyroxine and metformin. However, there was no interaction when patiromer and these medicinal products were taken 3 hours apart.

This information is not inclusive of all prescribing information, potential adverse effects and drug interactions. Please refer to full prescribing data in the Summary of Product Characteristics or the British National Formulary.

[1] NICE TA623 February 2020
[2] Summary of Product Characteristics https://www.medicines.org.uk/emc/product/779#gref Accessed 30/06/2021