Veltassa® (patiromer sorbitex calcium)
Prescribing Information – Great Britain

For full prescribing information refer to the Summary of Product Characteristics (SmPC)

Active ingredient: patiromer sorbitex calcium

Presentation Powder for oral suspension available in sachets containing either 8.4g,16.8g.

Indication: Treatment of hyperkalaemia in adults.

Dosage and Administration: The recommended starting dose is 8.4 g administered orally once daily with or without food. The daily dose may be adjusted by 8.4 g as needed at one-week intervals or longer to reach desired serum potassium target range, up to a maximum dose of 25.2 g daily. If serum potassium falls below the desired range, the dose should be reduced or discontinued. If a dose is missed, the missed dose should be taken as soon as possible on the same day and should not be taken with the next dose. Administration of Veltassa should be separated by 3 hours from other oral medicinal products. The onset of action occurs 4–7 hours after administration. Veltassa should not replace emergency treatment for life-threatening hyperkalaemia. There is limited data on the use of Veltassa in patients on dialysis; no special dose and administration guidelines were applied to these patients in clinical studies. The complete dose should be poured into a glass containing approximately 40ml of water, then stirred. Another approximately 40ml of water should be added. And the suspension stirred again thoroughly. More water may be added to the mixture as needed for desired consistency. The mixture should be taken within 1 hour. Please consult the SmPC in relation to which liquids or soft foods can be used instead of water to prepare the mixture. The potassium content of liquids or soft foods used to prepare the mixture should be considered as part of the dietary recommendations on potassium intake for each individual patient.

Contraindications: Hypersensitivity to active ingredient or to the excipient xanthan gum.

Special warnings and precautions: serum magnesium should be monitored for at least 1 month after initiating treatment, and magnesium supplementation considered in patients who develop low serum magnesium levels. A risk/benefit evaluation is required in patients with current or a history of severe gastrointestinal disorders, before and during treatment. When discontinuing Veltassa, serum potassium levels may rise, especially if RAAS inhibitor treatment is continued, so patients should be instructed not to discontinue therapy without consulting their physician. Increases in serum potassium may occur as early as 2 days after the last dose. 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 dose titration. Veltassa contains sorbitol as part of the counterion complex (4 g per 8.4 g of patiromer), therefore patients with hereditary problems of fructose intolerance should not take this medicine. Veltassa contains calcium as part of the counterion complex; calcium is partially released, some of which may be absorbed therefore a risk/benefit evaluation is required in patients at risk of hypercalcaemia. There are limited clinical data in patients with end-stage renal disease and in patients with serum potassium concentrations greater than 6.5 mmol/L. Clinical trials with patiromer have not included exposure longer than one year.
Overdose: Veltassa is excreted after approximately 24-48 hours, based on average gastrointestinal transit time. Excessive doses may result in hypokalaemia, therefore serum potassium levels should be monitored.

Special populations: The use of Veltassa has not been studied in children under 18 years. Since there are no data from the use of patiromer in pregnant women, it is preferable to avoid the use of Veltassa during pregnancy. No special dose and administration guidelines are recommended for elderly population.
Undesirable effects: Common (≥1/100 to <1/10): Hypomagnesaemia, constipation, diarrhoea, abdominal pain, flatulence. Please consult the SmPC in relation to other undesirable effects.

Legal category: POM

Price: pack of 30 x 8.4g sachets = £172.50; pack of 30 x 16.8g sachets = £172.50

MA Number: PLGB 50784/0002, PLGB 50784/0003

Date of Authorisation: 19/07/2017

MA Holder: Vifor Fresenius Medical Care Renal Pharma France, 100-101 Terrasse Boieldieu, Tour Franklin La Défense 8, 92042 Paris La Défense Cedex, France

Veltassa® is a registered trademark

Document number: UK-PAT-2400001
Date of preparation: January 2024

Adverse events should be reported. Reporting forms and information for Great Britain can be found at https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Vifor Fresenius Medical Care Renal Pharma, care of Vifor Pharma Ltd. Tel: +44 1276 853633. E-mail: medicalinfo_UK@viforpharma.com

Veltassa® (patiromer sorbitex calcium)
Prescribing Information – Northern Ireland

For full prescribing information refer to the Summary of Product Characteristics (SmPC)

Active ingredient: patiromer sorbitex calcium

Presentation Powder for oral suspension available in sachets containing either 8.4g,16.8g.

Indication: Treatment of hyperkalaemia in adults and adolescents aged 12 to 17 years

Dosage and Administration: The recommended starting dose varies with age and is administered orally once daily. Multiple sachets may be used to achieve the desired dose with or without meals. In adults, the starting dose is 8.4 g once daily and it may be adjusted by 8.4 g as needed at one-week intervals or longer to reach desired serum potassium target range, up to a maximum dose of 25.2 g daily.
In *adolescents aged 12 to 17 years, t*he recommended starting dose is 4 g once daily and this may be adjusted as needed at one-week intervals or longer to reach desired serum potassium target range, up to a maximum dose of 25.2 g daily. If serum potassium falls below the desired range, the dose should be reduced or discontinued. If a dose is missed, the missed dose should be taken as soon as possible on the same day and should not be taken with the next dose. Administration of Patiromer should be separated by 3 hours from other oral medicinal products. The onset of action occurs 4–7 hours after administration. Patiromer should not replace emergency treatment for life-threatening hyperkalaemia. There is limited data on the use of Patiromer in patients on dialysis; no special dose and administration guidelines were applied to these patients in clinical studies. The suspension should be should be prepared according to the following steps; the first half of the recommended volume for the required dose should be poured into a glass and the complete dose of patiromer should be added, then stirred. The second half of the recommended volume should be added and the suspension stirred again thoroughly. More water may be added to the mixture as needed for desired consistency. The mixture should be taken within 1 hour. Please consult the SmPC in relation to which liquids or soft foods can be used instead of water to prepare the mixture. The potassium content of liquids or soft foods used to prepare the mixture should be considered as part of the dietary recommendations on potassium intake for each individual patient.

Contraindications: Hypersensitivity to active ingredient or to the excipient xanthan gum.

Special warnings and precautions: serum magnesium should be monitored for at least 1 month after initiating treatment, and magnesium supplementation considered in patients who develop low serum magnesium levels. A risk/benefit evaluation is required in patients with current or a history of severe gastrointestinal disorders, before and during treatment. When discontinuing Patiromer, serum potassium levels may rise, especially if RAAS inhibitor treatment is continued, so patients should be instructed not to discontinue therapy without consulting their physician. Increases in serum potassium may occur as early as 2 days after the last dose. 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 dose titration or discontinuation. Patiromer contains sorbitol as part of the counterion complex (4 g per 8.4 g of patiromer), therefore patients with hereditary problems of fructose intolerance should not take this medicine. Patiromer contains calcium as part of the counterion complex; calcium is partially released, some of which may be absorbed therefore a risk/benefit evaluation is required in patients at risk of hypercalcaemia. Serum calcium should be monitored for at least 1 month after initiating treatment. There are limited clinical data in patients with serum potassium concentrations greater than 6.5 mmol/L. Clinical trials with patiromer have not included exposure longer than one year. Clinical trials in paediatric patients have not included exposure longer than 6 months. Interaction studies have only been performed in adults.

Overdose: Patiromer is excreted after approximately 24-48 hours, based on average gastrointestinal transit time. Excessive doses may result in hypokalaemia, therefore serum potassium levels should be monitored.

Special populations: The use of Patiromer has not been studied in patients under 6 years of age. Since there are no data from the use of patiromer in pregnant women, it is preferable to avoid the use of Patiromer during pregnancy. No special dose and administration guidelines are recommended for elderly population.

Undesirable effects: Common (≥1/100 to <1/10): Hypomagnesaemia, constipation, diarrhoea, abdominal pain, flatulence. Please consult the SmPC in relation to other undesirable effects.

Legal category: POM

Price: pack of 30 x 8.4g sachets = £172.50; pack of 30 x 16.8g sachets = £172.50; 25.2g=not available in Northern Ireland; 1g sachets=not available in Northern Ireland

MA Number: EU/1/17/1179/001, EU/1/17/1179/004, EU/1/17/1179/007, EU/1/17/1179/011

Date of Authorisation: 19/07/2017

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