Abbreviated prescribing information Veltassa®

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

Presentation and active ingredient: Patiromer (as patiromer sorbitex calcium) powder for oral suspension available in sachets containing either 8.4 g, 16.8 g or 25 2 g

Indication: Treatment of hyperkalaemia in adults.

Dosage and administration: The recommended starting dose of Veltassa® 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. Veltassa® may affect certain oral medicines taken at the same time, such as ciprofloxacin, levothyroxine, metformin and quinidine and therefore Veltassa® administration should be separated by at least 3 hours from other oral medicinal products. The onset of action of Veltassa® 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.

Contraindications: Hypersensitivity to the active substance or to any of the excipients listed in section 6.1 (refer to the SmPC)

Special warnings and precautions: Due to potential hypomagnesaemia, 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 physicians. Increases in serum potassium may occur as early as 2 days after the last Veltassa® 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 Veltassa® dose is titrated. Veltassa® contains sorbitol as part of the counterion complex (4.0 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 hypercalcemia. There are limited clinical data in patients with end-stage renal disease and in patients with serum potassium concentrations greater than 6.5 mEq/L.

Overdosage: Since excessive doses of Veltassa® may result in hypokalaemia, 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 ls 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 /1 O): hypomagnesaemia, constipation, diarrhea, abdominal pain, flatulence. Please consult the SmPC in relation to other undesirable effects.

Prescription Only Medicine. Full prescribing information is available on request. Please read the full SmPC prior to administration Veltassa® is a registered trademark

Saudi Leaflet revision date: October 2020

Kuwait Leaflet revision date: July 2017

UAE Leaflet revision date: April 2021

MA Holder: OM Pharma SA, R. da lndustria, 2, 2610-088, Quinta Grande, Amadora, Portugal

For any further information or inquiries please refer to full SMPC to any product.

For Saudi

Adverse events should be reported to:

- National Pharmacovigilance, E-mail: npc.drug@sfda.gov.sa
- Our local Saudi representative of the Marketing Authorisation Holder:
  ARAC Healthcare, Address City: Riyadh, Tel:+ 966 11 417 1596, e-mail: Drug.safety@arac.sa
- Vifor International Rep. office through safety@viforpharma.com

For Other Gulf markets

Adverse events should be reported to:

- Vifor International Rep. office through safety@viforpharma.com

Vifor International Rep. Office address:

Vifor international AG rep office, Aspin Commercial Building,

33rd floor Office 3301, Sheikh Zayed road P.O. Box 414087, Tel; +971 (4) 352 3774.

Veltassa® (patiromer) for oral suspension