Parsabiv® ▼ (etelcalcetide) Brief Prescribing Information

Please refer to the Summary of Product Characteristics (SmPC) before prescribing Parsabiv. **Pharmaceutical Form:** Parsabiv contains etelacalcetide (as hydrochloride) 5 mg/ml solution for injection in vials of 2.5 mg, 5 mg and 10 mg. **Indication:** Parsabiv is indicated for the treatment of secondary hyperparathyroidism (SHPT) in adult patients with chronic kidney disease (CKD) on haemodialysis therapy. **Dosage and Administration:** The recommended initial dose of etelcalcetide is 5 mg administered 3 times per week. Corrected serum calcium should be at or above the lower limit of the normal range prior to administration of first dose of Parsabiv, a dose increase, or reinitiation after a dose stop. Parsabiv should not be administered more frequently than 3 times per week. Parsabiv should be titrated so that doses are individualised between 2.5 mg and 15 mg 3 times per week to achieve the desired parathyroid hormone (PTH) target, while maintaining serum calcium at or above the lower limit of normal. The dose may be increased in 2.5 mg or 5 mg increments no more frequently than every 4 weeks. PTH should be measured after 4 weeks from initiation or dose adjustment, and approximately every 1-3 months during maintenance. Serum calcium should be measured within 1 week of initiation or dose adjustment and approximately every 4 weeks during maintenance. If clinically meaningful decreases in corrected serum calcium levels occur, steps should be taken to increase serum calcium levels. Please refer to the Parsabiv SmPC for further details on dose adjustments based on PTH and calcium levels. Parsabiv may be used in combination with phosphate binders and/or vitamin D sterols. If a regularly scheduled haemodialysis treatment is missed, do not administer any missed doses. Parsabiv should not be initiated in patients until 7 days after the last dose of cinacalcet. **Method of administration:** Parsabiv is administered by bolus injection into the venous line of the dialysis circuit at the end of the haemodialysis treatment during rinse-back, or intravenously after rinse-back. When given during rinse-back, at least 150 mL of rinse-back volume should be administered after injection. If rinse-back is completed and Parsabiv was not administered, then it may be administered intravenously followed by at least 10 mL saline flush volume. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. Parsabiv should not be initiated if corrected serum calcium is less than the lower limit of the normal range. **Special Warnings and Precautions:** Hypocalcaemia: Parsabiv treatment should not be initiated in patients if the corrected serum calcium is less than the lower limit of the normal range. Potential manifestations of hypocalcaemia include paraesthesias, myalgias, muscle spasm and seizures. Since etelcalcetide lowers serum calcium, patients should be advised to seek medical attention if they experience symptoms of hypocalcaemia and should be monitored for the occurrence of hypocalcaemia. Serum calcium levels should be closely monitored in patients with congenital long QT syndrome, previous history of QT prolongation, family history of long QT syndrome or sudden cardiac death and other conditions that predispose to QT prolongation and ventricular arrhythmia. Serum calcium levels should be closely monitored in patients with a history of a convulsion disorder. Worsening heart failure: Serum calcium levels should be monitored in patients with a history of congestive heart failure. Co-administration with other medicinal products: Administer Parsabiv with caution in patients receiving any other medicinal products known to lower serum calcium. Patients receiving Parsabiv should not be given cinacalcet. Concurrent administration may result in severe hypocalcaemia. Adynamic bone: Adynamic bone may develop if PTH levels are chronically suppressed below 100 pg/mL. If PTH levels decrease below the recommended target range, the dose of vitamin D sterols and/or Parsabiv should be reduced or therapy discontinued. Immunogenicity: No evidence of altered pharmacokinetic profile, clinical response or safety profile was associated with pre-existing or developing anti-etelcalcetide antibodies. **Interactions:** No interaction studies have been performed. There is no known risk of pharmacokinetic interaction with etelcalcetide. **Fertility, pregnancy and lactation:** There are no or limited data from the use of etelcalcetide in pregnant women. It is preferable to avoid the use of Parsabiv during pregnancy. It is unknown whether etelcalcetide is present in human milk. A risk to breastfed newborns/infants cannot be excluded. No data are available on the effect of etelcalcetide on human fertility. **Undesirable Effects:** The incidence of adverse reactions from controlled clinical studies are: very common (≥ 1/10) blood calcium decreased, nausea, vomiting, diarrhoea and muscle spasms; common (≥ 1/100 to < 1/10) hypocalcaemia, hyperkalaemia, hypophosphataemia, headache, paraesthesia, worsening heart failure, QT prolongation, hypotension and myalgia. Please refer to the Parsabiv SmPC for further information on undesirable effects**. Pharmaceutical Precautions:** Store in a refrigerator (2°C – 8°C). Keep the vial in the outer carton to protect from light. Clear colourless solution. For single use only. **Legal Category:** POM. **Presentation, Basic Costs and Marketing Authorisation Number:**

Parsabiv 2.5 mg solution for injection Pack of 6 vials: £136.87; EU/1/16/1142/002.

Parsabiv 5 mg solution for injection Pack of 6 vials: £163.92; EU/1/16/1142/006.

Parsabiv 10 mg solution for injection Pack of 6 vials: £327.84; EU/1/16/1142/010.

Marketing Authorisation Holder: Amgen Europe B.V. Minervum 7061, 4817 ZK Breda, The Netherlands. Further information is available from Amgen Limited, 240 Cambridge Science Park, Milton Road, Cambridge, CB4 0WD. Parsabiv is a registered trademark of Amgen Inc. **Date of PI preparation:** December 2016 (Ref:UKIE-P-416-1216-042520).

This medicinal product is subject to additional monitoring. Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard.

Adverse events should also be reported to Amgen Limited on +44 (0) 1223 436441.