

Yorvipath▼ (palopegteriparatide) Prescribing Information for HCPs in Great Britain (GB)

(Please consult the full Summary of Product Characteristics (SmPC) before prescribing)

**Presentation:** Yorvipath 168mcg/0.56mL solution for injection in pre-filled pen. Yorvipath 294mcg/0.98mL solution for injection in pre-filled pen. Yorvipath 420mcg/1.4mL solution for injection in pre-filled pen. The concentration based on PTH (1-34) is 0.3mg/mL. **Indication:** Indicated for the treatment of adults with chronic hypoparathyroidism. **Posology and method of administration:** Please refer to SmPC for full information. Should be initiated and monitored by physicians or qualified healthcare professionals experienced in the diagnosis and management of patients with hypoparathyroidism. Dose recommendations refer to micrograms of PTH(1-34). The dose should be individualised based on serum calcium. The optimal dose after titration is the minimum dose required to prevent hypocalcaemia. Patients receiving the maximum dose of 60mcg per day who experience ongoing hypocalcaemia may require co-administration of therapeutic calcium and/or active forms of vitamin D. **Before initiation:** Serum 25(OH) vitamin D should be within the normal range and serum calcium should be stable within or slightly below the normal range (1.95-2.64mmol/L) on at least 1 laboratory value at least two weeks prior to first dose of treatment. **Initiation:** Recommended starting dose is 18mcg once daily with dose adjustments in 3mcg increments thereafter every 7 days. The dose range is 6 to 60mcg per day. When initiating treatment, the dose of active Vitamin D or calcium supplements should be adjusted. **If taking active Vitamin D:** If serum calcium is  $\geq 2.07$ mmol/L, active Vitamin D (calcitriol or alfacalcidol) should be discontinued on the same day as the first dose. Doses of calcium supplements should be maintained. If serum calcium  $< 2.07$ mmol/L, active vitamin D should be reduced by  $\geq 50\%$  on the same day as the first dose. Doses of calcium supplements should be maintained. **If not taking active vitamin D:** Calcium supplements should be decreased by at least 1500mg on the same day as the first dose. If taking elemental calcium doses  $\leq 1500$ mg per day, calcium supplements should be discontinued entirely. If calcium supplements are indicated to meet dietary requirements, continuing dietary calcium supplements at doses  $\leq 600$ mg per day may be considered instead of discontinuing entirely. **Maintenance:** Maintenance dose should be the dose that achieves serum calcium within the normal range, without the need for active vitamin D or therapeutic doses of calcium. Optionally, calcium supplementation sufficient to meet dietary requirements ( $\leq 600$ mg per day) may be continued. Serum calcium and 25(OH) vitamin D should be measured as per standard of care when a maintenance dose is achieved. 25(OH) vitamin D (non-active vitamin D) supplementation may be needed to reach normal serum levels. **Missed dose:** If a dose is missed by less than 12 hours, it should be administered as soon as possible. If missed by more than 12 hours, it should be skipped and the next dose should be administered as scheduled. **Interruption or discontinuation:** This should be avoided to minimise serum PTH fluctuations and can also result in hypocalcaemia. When interrupting or

discontinuing treatment for 3 or more consecutive doses, patients should be monitored for signs and symptoms of hypocalcaemia and consider measuring serum calcium. If indicated, treatment with calcium supplements and active vitamin D should be resumed. Treatment at the prescribed dose should be resumed as soon as possible after an interruption. *Elderly*: Dose adjustment is not required based on age. *Hepatic impairment*: There are no data in patients with severe hepatic impairment and should be used with caution in these patients. *Renal impairment*: Dose adjustment is not required in patients with an estimated glomerular filtration rate (eGFR)  $\geq$  30mL/min. Serum calcium levels should be measured more frequently when used in patients with eGFR < 45 mL/min. There are no data in patients with hypoparathyroidism and severe renal impairment (eGFR < 30mL/min). *Paediatric population*: Safety and efficacy in children less than 18 years of age have not yet been established. No data available. **Contraindications**: Hypersensitivity to the active substance or to any of the excipients. Patients with pseudohypoparathyroidism. **Special warnings and precautions for use**: *Hypercalcaemia*: Serious events have been reported with treatment. Risk is highest when starting or increasing the dose. Serum calcium should be measured during treatment and patients monitored for signs and symptoms of hypercalcaemia. If severe hypercalcaemia occurs, treatment should be as per clinical guidelines and dose adjustment considered. *Hypocalcaemia*: Serious events have been reported with the risk being highest when treatment is abruptly discontinued but may occur at any time. Serum calcium should be measured during treatment and patients monitored for signs and symptoms of hypocalcaemia. If severe hypocalcaemia occurs, treatment should be as per clinical guidelines, dose adjustment considered and dose adjustment of standing or as needed doses of active vitamin D and/or calcium supplements should also be considered. *Concomitant use with cardiac glycosides*: Hypercalcaemia of any cause may predispose to digitalis toxicity. In treated patients concomitantly using cardiac glycosides (digoxin/digitoxin), serum calcium and cardiac glycoside levels should be monitored and patients observed for signs and symptoms of digitalis toxicity. *Severe renal or hepatic disease*: No studies have been performed in these patients. Use with caution in these patient populations. Patients with eGFR of <45mL/min may be more susceptible for hypercalcaemic reactions and transient eGFR decrease; particularly when initiating treatment, therefore it is recommended to closely monitor serum calcium levels. *Use in patients at increased risk of osteosarcoma*: Treatment has not been studied in and should be used with caution in patients with skeletal malignancies and bone metastases; who are receiving or who have received radiation therapy to the skeleton; with unexplained elevations of bone-specific alkaline phosphatase; with metabolic bone diseases who are at increased baseline risk for osteosarcoma (eg Paget's disease of the bone). *Use in patients with osteoporosis*: Screening for and monitoring of osteoporosis should be consistent with local clinical practice for any patient at increased risk of fragility fractures. *Sodium content*: This product contains less than 1 mmol sodium (23mg) per dose; essentially 'sodium-free'. **Interaction with other medicinal products and other forms of interaction**: No interaction studies have been performed. Cardiac

glycosides (digoxin/digitoxin) have a narrow therapeutic index and are affected by calcium. Patients taking cardiac glycosides should be monitored for signs and symptoms of digitalis toxicity. Other medicinal products can exert effects on serum calcium and may alter the therapeutic response, including but not limited to bisphosphonates, denosumab, romosozumab, thiazide and loop diuretics, systemic corticosteroids, and lithium. Patients should be monitored for changes in serum calcium when treated concomitantly with these medicinal products. **Fertility, pregnancy and lactation:** *Pregnancy:* No/limited data. Animal studies do not indicate direct or indirect harmful effects. Risks to the mother or foetus cannot be excluded. Treatment decisions should weigh potential risks and benefits. Maternal serum calcium levels should be closely monitored in pregnant females with hypoparathyroidism and with treatment. *Breast-feeding:* It is unknown if palopegteriparatide is excreted in human milk. As it is not orally absorbed, it is unlikely to adversely affect the breast-fed child. A decision to discontinue breast-feeding whilst on treatment should consider the benefit of breast-feeding for the child and benefit of therapy for the female. Closely monitor maternal serum calcium levels if breast-feeding with hypoparathyroidism and with treatment. *Fertility:* No studies have been performed. Data from animal studies do not indicate that administration impairs fertility. **Effects on ability to drive and use machines:** There is no negligible influence on the ability to drive and use machines. Dizziness, presyncope, syncope and/or orthostatic hypotension was observed in some patients. Patients should refrain from driving or the use of machines until symptoms have subsided. **Undesirable effects:** *Very common ( $\geq 1/10$ ):* Headache, paraesthesia, nausea, injection site reactions, fatigue. *Common ( $\geq 1/100$  to  $< 1/10$ ):* Hypercalcaemia, hypocalcaemia, dizziness, syncope, presyncope, palpitations, postural orthostatic tachycardia syndrome, orthostatic hypotension, oropharyngeal pain, diarrhoea, constipation, vomiting, abdominal discomfort, abdominal pain, rash, photosensitivity reaction, arthralgia, myalgia, muscle twitching, musculoskeletal pain, asthenia, thirst. *Uncommon:* Hypertension, nocturia, chest discomfort, chest pain. *Frequency not known:* Polyuria, bone density decreased. Refer to SmPC for further information on adverse reactions. **Overdose:** Monitor carefully. **Pharmaceutical Particulars:** Store in a refrigerator (2°C - 8°C), Do not freeze. **Legal Category:** POM. **Presentation and Basic NHS cost:** Yorvipath 168mcg/0.56mL solution for injection in pre-filled pen, Yorvipath 294mcg/0.98mL solution for injection in pre-filled pen, Yorvipath 420mcg/1.4mL solution for injection in pre-filled pen £7,406 per pack (2x pre-filled pens). **Marketing Authorisation Number:** PLGB51127/0001/0002/0003. **Marketing Authorisation Holder:** Ascendis Pharma Bone Diseases A/S Tuborg Boulevard 12 DK-2900 Hellerup, Denmark. **Job Code:** UK-COMMPH-2500065 **Date of Revision:** September 2025

**Adverse events should be reported. Reporting forms and information can be found at <https://yellowcard.mhra.gov.uk/> or search for MHRA Yellowcard in the Google Play or Apple App Store. Adverse events should also be reported to Ascendis Pharma UK on [medinfo-UK@ascendispharma.com](mailto:medinfo-UK@ascendispharma.com)**

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