

YORVIPATH (palopegterlparatide)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Yorvipath (palopegterlparatide) releases parathyroid hormone (PTH) (1-34) to maintain a continuous systemic exposure. Endogenous PTH maintains extracellular calcium and phosphate homeostasis by increasing serum calcium and decreasing serum phosphate. These effects are mediated by stimulating bone turnover to mobilize calcium and phosphate from bone, promoting renal calcium reabsorption and phosphate excretion, and facilitating active vitamin D synthesis, in turn increasing intestinal absorption of calcium and phosphate. Similar to endogenous PTH, PTH (1-34) released from Yorvipath exerts these effects through its main receptor, parathyroid hormone 1 receptor (PTH1R), which is highly expressed on osteoblasts, osteocytes, renal tubular cells, and in several other tissues (1).

Regulatory Status

FDA-approved indication: Yorvipath is a parathyroid hormone analog (PTH (1-34)) indicated for the treatment of hypoparathyroidism in adults (1).

Limitations of Use: (1)

1. Not studied for acute post-surgical hypoparathyroidism.
2. Titration scheme only evaluated in adults who first achieved an albumin-corrected serum calcium of at least 7.8 mg/dL using calcium and active vitamin D treatment.

Yorvipath carries warnings for changes in serum calcium levels, serious hypercalcemia and hypocalcemia, risk of osteosarcoma, orthostatic hypotension, and digoxin toxicity. Using more than one injection to achieve the recommended daily dose can increase the variability of the total delivered dose, which can cause unintended changes in serum calcium. Therefore, use one injection to achieve the recommended once daily dose. Serum calcium should be measured 7 to 10 days after any change in dose or if signs and symptoms of hypercalcemia or hypocalcemia are present. Once maintenance dosage is achieved, serum calcium levels should be measured every 4 to 6 weeks. Yorvipath is not recommended in patients at risk for osteosarcoma. Yorvipath should be administered when the patient can sit or lie down due to the potential of orthostatic hypotension. Since Yorvipath increases serum calcium, concomitant digoxin use may predispose patients to digitalis toxicity if hypercalcemia develops. Serum calcium and digoxin levels should be measured



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routinely, and dosing should be adjusted if needed (1).

The safety and effectiveness of Yorvipath in pediatric patients less than 18 years of age have not been established (1).

Summary

Yorvipath is a parathyroid hormone analog (PTH (1-34)) indicated for the treatment of hypoparathyroidism. Yorvipath carries warnings for changes in serum calcium levels, serious hypercalcemia and hypocalcemia, risk of osteosarcoma, orthostatic hypotension, and digoxin toxicity. The safety and effectiveness of Yorvipath in pediatric patients less than 18 years of age has not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Yorvipath while maintaining optimal therapeutic outcomes.

References

1. Yorvipath [package insert]. Hellerup, Denmark: Ascendis Pharma Bone Diseases A/S; August 2024.