Rocaltrol® (calcitriol) 0.25 and 0.5 microgram capsules Prescribing Information

Please consult the full Summary of Product Characteristics (SmPC) before prescribing
Presentation: Each Rocaltrol capsule contains either 0.25 or 0.5 micrograms (mcg) of calcitriol. **Indication:** Rocaltrol is indicated for the correction of the abnormalities of calcium and phosphate metabolism in patients with renal osteodystrophy. Rocaltrol is also indicated for the treatment of established post-menopausal osteoporosis. **Dosage and administration:** The dose of Rocaltrol should be adjusted for each patient according to biological response, so as to avoid hypercalcaemia. Treatment effectiveness depends in part on adequate daily intake of calcium, which should be augmented by dietary changes or supplements if necessary. Capsules to be swallowed with a little water.
Renal osteodystrophy (adults including elderly): Initial daily dose is 0.25 mcg. In patients with normal or only slightly reduced calcium levels, doses of 0.25 mcg every other day are sufficient. The daily dosage may be increased by 0.25 mcg at 2-4 week intervals if no satisfactory response is observed within 2-4 weeks. During this period serum calcium levels should be determined at least twice weekly. If serum calcium levels rise to 1mg/100ml (250 μmol/l) above normal or serum creatinine rises to >120 μmol/l, Rocaltrol should be stopped immediately until normocalcaemia ensues. Most patients respond to doses between 0.5 mcg and 1.0 mcg daily. In patients with renal osteodystrophy refractory to continuous therapy see details in SmPC for pulse therapy dose option.
Post-menopausal osteoporosis (adults including elderly): Recommended dose is 0.25 mcg twice daily. Serum calcium and creatinine levels should be determined at 1, 3 and 6 months and 6 monthly thereafter. *Children:* Limited data available for calcitriol capsules use in paediatric patients. Unable to make dosing recommendations.
Contraindications: Diseases associated with hypercalcaemia; patients with evidence of metastatic calcification; known hypersensitivity to calcitriol or any excipients in Rocaltrol; evidence of vitamin D toxicity. **Special warnings and precautions:** Dose correlation between calcitriol and development of hypercalcaemia exists. Withhold all other vitamin D compounds or derivatives during Rocaltrol treatment. Due to potential for an abrupt increase in dietary calcium intake to trigger hypercalcaemia, patients and their families should be advised that strict hypercalcaemia. If serum calcium levels rise to 1mg/100ml (250 μmol/l) above normal or serum creatinine rises to > 120 μmol/l, Rocaltrol should be stopped immediately until normocalcaemia ensues. Immobilised patients are particularly at risk of hypercalcaemia. Uncontrolled intake of additional calcium-containing preparations to be avoided. Calcitriol increases serum inorganic phosphate levels. In patients with renal failure, plasma phosphate levels should be maintained at the normal level, by use of oral phosphate binding agents and low phosphate diet. Serum calcium times phosphate (Ca x P) product should not exceed 70 mg^2/dl^2. No other vitamin D preparation should be prescribed during Rocaltrol treatment. Caution is needed when patient is switched from long acting vitamin D preparation or is on concomitant thiazide diuretic due to increased risk of hypercalcaemia. Patients with vitamin D-resistant rickets should continue oral phosphate therapy, but may require adjustment of phosphate supplements. Patients on chronic renal dialysis should not take magnesium containing drugs whilst on Rocaltrol. Patients with normal renal function taking Rocaltrol should avoid dehydration. In those with normal renal function, chronic hypercalcaemia may be associated with an increase in serum creatinine. Due to sorbitol content, patients with rare hereditary problems of fructose intolerance should not take Rocaltrol. **For further information on special warnings, precautions and interactions please refer to SmPC.**
Pregnancy and lactation: Rocaltrol should be used in pregnancy only if benefits outweigh risk to foetus. Whilst breastfeeding, mother and infant serum calcium levels to be monitored.
Undesirable effects: *Very common (≥1/10):* hypercalcaemia; *Common* (≥1/100 to <1/10): Headache, abdominal pain, nausea, rash and urinary tract infection. Hypersensitivity reactions may occur. **Please refer to SmPC for full details**.
Legal category: POM **Presentation and cost:** 0.25 mcg (100 capsules) £18.04; 0.5 mcg (100 capsules) £32.25.
Marketing authorisation holder and numbers: Atnahs Pharma UK Limited, Sovereign House, Miles Gray Road, Basildon SS14 3FR, UK.
PL 43252/0028 (0.25 mcg) and 43252/0029 (0.5 mcg).
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Adverse events should be reported. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Atnahs Pharma UK Limited on +44 (0) 1279 406759 or by email to atnahspv@diamondpharmaservices.com