

Rocal-D[®]

Calcium & Cholecalciferol (Vitamin-D₃)

Presentation

Rocal-D[®] Tablet: Each film-coated tablet contains calcium carbonate USP 1250 mg equivalent to 500 mg of elemental calcium and cholecalciferol (vitamin-D₃) USP 200 IU.

Description

Calcium is an essential element and plays vital roles in the body. It makes body's framework stronger by building bone. Clinical evidence suggests that calcium is useful for prevention and treatment of osteoporosis and associated fractures. Vitamin-D₃ is also essential for healthy bones as it aids in calcium absorption from the GI tract. In addition to this it stimulates bone formation. Controlled clinical studies show that calcium and vitamin-D₃ have synergistic effects on bone growth as well as in osteoporosis and fracture prevention.

Indication and uses

- Treatment of osteoporosis, rickets, osteomalacia, tetany and hypoparathyroidism.
- In pregnancy and lactation due to increase demand.
- In kidney disease and pancreatitis.
- During therapy with antiseizure medications.
- The prevention and treatment of calcium deficiency/vitamin-D₃ deficiency especially in the housebound and institutionalized elderly subjects.

Dosage and administration

Adults and elderly and children 12 years of age:

2 tablets per day, preferably one tablet each morning and evening.

Children:

Not recommended for children under 12 years.

Side effects

The use of calcium supplements has rarely given rise to mild gastro-intestinal disturbances such as constipation, flatulence, nausea, gastric pain, diarrhea. Following administration of vitamin-D₃ supplements occasional skin rash has been reported. Hypercalcaemia and in rare cases hypercalcaemia have been seen with long term treatment at high dosages.

Precautions

Patients with mild to moderate renal failure or mild hypercalcaemia should be supervised carefully. Periodic checks of plasma calcium levels and urinary calcium excretion should be made in patients with mild to moderate renal failure or mild hypercalcaemia. Urinary calcium excretion should also be measured. In patients with a history of renal stones urinary calcium excretion should be measured to exclude hypercalcaemia. With long term treatment it is advisable to monitor serum and urinary calcium levels and kidney function, and reduce and stop treatment temporarily if urinary calcium exceeds 75 mmol/24 hours. Allowances should be made for calcium and vitamin-D₃ supplements from other sources.

Pregnancy and lactation

During pregnancy and lactation treatment should always be under the direction of a physician. During pregnancy and lactation, requirements for calcium and vitamin-D₃ are increased but in deciding on the required supplementation allowances should be made

for availability of these agents from other sources. If calcium and iron supplements are both required to be administered to the patient, they should be taken at different times. Overdoses of vitamin-D₃ have shown teratogenic effects in pregnant animals. In humans long term hypercalcaemia can lead to physical and mental retardation, aortic stenosis and retinopathy in a new born child. Vitamin-D₃ and its metabolites pass into the breast milk.

Contraindications

Absolute contraindications are hypercalcaemia resulting for example from myeloma, bone metastases or other malignant bone disease, sarcoidosis; primary hyperparathyroidism and Vitamin-D₃ overdose. Severe renal failure. Hypersensitivity to any of the tablet ingredients.

Relative contraindications are osteoporosis due to prolonged immobilisation, renal stones, severe hypercalcaemia.

Drug Interaction

The risk of hypocalcaemia should be considered in patients taking thiazide diuretics since these drugs can reduce urinary calcium excretion. Hypocalcaemia must be avoided in digitalised patients. Certain foods (e.g. those containing oxalic acid, phosphate or phytinic acid) may reduce the absorption of calcium. Concomitant treatment with phenytoin or barbiturates can decrease the effect of Vitamin-D₃ because of metabolic activation. Concomitant use of glucocorticoids can decrease the effect of Vitamin-D₃. The effects of digitalis and other cardiac glycosides may be attenuated with the oral administration of calcium combined with Vitamin-D₃. Strict medical supervision is needed and, if necessary monitoring of ECG and calcium. Calcium salts may reduce the absorption of thyroxin, bisphosphonates, sodium fluoride, quinolone or tetracycline antibiotics or iron. It is advisable to allow a minimum period of four hours before taking the calcium.

Overdosage

The most serious consequences of acute or chronic overdose is hypocalcaemia due to Vitamin-D₃ toxicity. Symptoms include nausea, vomiting, polyuria and constipation. Chronic overdose can lead to vascular and organic calcification as a result of hypocalcaemia. Treatment should consist of stopping all intakes of calcium and Vitamin-D₃ and rehydration.

Storage

Store below 25 °C in a cool and dry place. Protect from light.

Packaging

Box containing 6x10's tablet in blister pack.

Medicine: Keep out of reach of children



Healthcare

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