

ORAL D

Powder

Composition

Each oral ampoule contains Vitamin D 15000 I.U.

Action

Vitamin D best characterized as a positive regulator of calcium homeostasis. The vitamin in a manner parallel to that of calcium affects phosphate metabolism. The mechanism by which Vitamin D acts to maintain normal concentrations of calcium and phosphate in plasma are to facilitate their absorption by the small intestine, to interact with parathyroid hormone to enhance their mobilization from bone, and to decrease their excretion by the kidney.

Vitamin D is essential for normal calcification of bone. Normal bone formation occurs when calcium and phosphate concentrations in the plasma are adequate.

Pharmacokinetics

Vitamin D substances are well absorbed from the gastro intestinal tract. The presence of bile is essential for adequate intestinal absorption.

Absorbed Vitamin D circulates in the blood in association with Vitamin D - binding protein.

The vitamin disappears from the plasma with a half-life of 19 to 25 hours but is stored in fat depots for prolonged periods. The primary route of excretion of Vitamin D is the bile.

Vitamin D and its metabolites undergo extensive enterohepatic recirculation.

Indications

Oral D is indicated in Vitamin D deficiency states, including malabsorption, hypocalcaemia, hypoparathyroidism, metabolic disorders, infantile and trasy rickets, rickets associated with intercurrent infectious diseases (especially those affecting the tracheobronchial tree and the lungs: whooping cough, bronchopneumonia, pneumonia,...etc.) disorders of dentition and dental caries, spasmophillia, and tetany.

In autumn as a preventive measure, to offset to some extent the lack of sunshine during winter.

Osteomalacia due to prolonged use of anticonvulsants, osteoporosis, familial hypophosphataemia, pagets disease, knitting of fractures, lupus vulgaris, cutaneous tuberculosis, scrofula, lymphatism adenitis, tuberculous adenitis and peritonitis.

Disturbances of growth, anemia and infantile asthenia. Psoriasis, Wilson's lichen planus and postoperative tetanus.

Contraindications

- Vitamin D contraindicated in the treatment of patients with coronary disease, impaired renal function, and arteriosclerosis, especially in the elderly.
- Large doses of Vitamin D are potentially dangerous and frequent determinations for calcium in blood and urine are mandatory.
- It is contraindicated in patients with hypercalcemia or evidence of Vit D toxicity.

Warnings

Any of Vit D derivatives must be withheld during treatment with Oral D.

Calcium and phosphorous levels must be monitored regularly to prevent any complications.

Adverse Reactions

Side effects of Oral Vit D are associated with hypercalcemia.

Early signs are weakness, nausea, vomiting, constipation, and muscle and bone pain. The late signs may be polyuria, anorexia, irritability, photophobia, elevated SGOT and SGPT.

Precautions

Excessive dosage of Oral D may cause hypercalcemia and hypercalciuria. Dose needs should be adjusted.

Oral D must be given with caution to patients receiving digitalis.
Oral D interacts with cholestyramine, anticonvulsants, and barbiturates.
Usage in pregnancy and lactating periods is not recommended.

Dosage and Administration

It is best taken on an empty stomach or two hours after meals.

Adults and Adolescent dose

Vitamin D deficiency

1000 to 2000 Units per day, the dosage being reduced to 400 Units per day when appropriate.

Vitamin D resistant rickets

12,000 to 500,000 Units per day.

Vitamin D dependent rickets

10,000 to 60,000 Units per day (up to 500,000 Units per day).

Osteomalacia due to prolonged use of anticonvulsants

1000 to 4000 Units per day.

Familial hypophosphataemia

50,000 to 100,000 Units per day.

Hypoparathyroidism

50,000 to 150,000 Units per day. In patients with renal function impairment, the dose is 40,000 to 100,000 Units per day. In patients with renal osteodystrophy, the initial dose is 20,000 Units and the maintenance dose is from 10,000 to 300,000 Units per day.

Pediatric dose

Vitamin D deficiency

1000 to 4000 Units per day, the dosage being reduced to 400 units per day when appropriate.

Vitamin D dependant rickets

3000 to 10,000 Units per day (up to 50,000 Units per day).

Osteomalacia due to prolonged use of anticonvulsants

1000 units per day.

Hypoparathyroidism

50,000 to 200,000 Units per day. In patients with renal osteodystrophy, the dosage is from 4000 to 40,000 units per day.

Over Dosage

Symptoms are hypercalcemia, hypercalciuria and hyperphosphatemia.

Treatment

Emesis or gastric lavage may be required.

Mineral oil can be used to enhance evacuation

Presentation

Oral ampoule of 15000 I.U.