Oravil®

VITAMIN D3 100,000 IU/ 2 ml
ORAL SOLUTION

Prescription drug Made in Argentina

Formula:
Each 100 ml of Oravil® contains: Cholecalciferol (Vitamin D3) 100,000 IU/ 2 ml, excipients: Vitamin E, Butylhydroxytoluen, Acid Saccharin, Corn Oil, Orange essence, Lemon essence, q.s.

Therapeutic Action:
Oral Vitamin D Therapy. It favors calcium and phosphate absorption, for normal bone calcification. Together with parathyroid hormone and calcitonin, it regulates calcemia by increasing calcium and phosphate plasma concentration.

Indications:
-Prevention and treatment of Vitamin D deficiency: rachitism, osteomalacia (softening of the bones),
-It is also indicated for the prevention and treatment of osteoporosis in patients with inadequate dietary Vitamin D and/or calcium intake.

Pharmacological Characteristics / Properties:
Vitamin D favors calcium and phosphate absorption and use for normal bone calcification. Skin exposure to UV light induces the formation of cholecalciferol (Vitamin D3). In the liver, cholecalciferol is turned into calcidiol, which is later transformed into calcitriol in the kidney (this is considered the most active form). Calcitriol seems to act by binding to a specific receptor in the cytoplasm of intestinal mucosa and is then incorporated into the nucleus, resulting in the formation of a protein that binds to calcium, increasing its absorption in the intestine. Together with parathyroid hormone, calcitriol regulates the calcium-ion transport from the bone to the extracellular fluid, achieving calcium homeostasis in this fluid.
It binds to a-globulines for the transport and it is mainly deposited in the liver and in fat reservoirs.

Calcitriol does not require metabolic activation and its degradation partially takes place in the kidney. Its plasma half-life is3 to 8 hours, its hypercalcemic action begins within 2 to 6 hours of administration (orally) and its concentration is achieved 2 hours after its administration. After its oral administration, its action lasts 1 to 2 days.

Dosage and Administration:
Vitamin D dosage must be adjusted to each particular case according to the doctor's opinion.
Prevention of rachitism in children up to 5 years old: One monodose vial every three months until the child is five years old. This dose may be doubled if the child is not much exposed to sunlight or in children with highly pigmented skin. Do not exceed 10 to 15 mg per year (that is, 4 to 6 monodose vials per year).
Vitamin deficiency prophylaxis in children and adolescents: one monodose vial every three months during a period with little exposure to sunlight.
Vitamin D deficiency prevention in pregnant women: one monodose vial administered only once towards the 6th month of pregnancy.
Vitamin D deficiency prevention in adults and elderly people: one monodose vial every 3 months.
Vitamin D deficiency treatment in adults and elderly people: one to two monodose vials per month.

Mode and route of administration:
Oral administration. The content of the monodose vial may be administered either in pure or in a slightly diluted form in water (it may become slightly turbid) or in milk in the milk bottle.

Contraindications:
Hypercalcemia, hypervitaminosis D, renal osteodystrophy with hyperphosphatemia. In addition, the risk-benefit ratio must be assessed in patients with: Arteriosclerosis, heart failure, hyperphosphatemia, hypersensitivity to Vitamin D, renal disease and sarcoidosis.

Precautions and warnings:
The margin between the therapeutic and the toxic dose is very narrow. Dose adjustment must be done immediately after a clinical improvement is observed. This drug must be taken under medical supervision. Dietary intake of Vitamin D fortified foods must be readjusted in order to avoid overdose disorders caused by Vitamin D or its analogs.

Pregnancy: No effects have been observed with the intake of Vitamin D daily requirements. However, the ingestion of excessive amounts of Vitamin D may pose a risk both for the mother and the unborn child. Pregnant women with hypersensitivity to the effects of Vitamin D may experience hypercalcemia, hypoparathyroidism and breastfeeding children may experience a particular facies syndrome, mental retardation and congenital aortic stenosis.
Breastfeeding: Although small amounts of Vitamin D metabolites can be found in human milk, no effects have been observed in human beings with the intake of normal daily requirements. Some breastfeeding children may be hypersensitive even at low doses of Vitamin D.
Use in pediatrics: Children who receive a long-term1,800 IU daily dose of Vitamin D, may experience growth failure. This drug must be taken under strict medical supervision with pediatric patients.
Use in elderly patients: The response of elderly patients to Vitamin D and its analogs is comparable to that of young adults.
Patients under anti-seizure therapy: Patients under anti-seizure therapy may require Vitamin D supplementation to prevent osteomalacia.

Drug-Drug Interactions:
Bisphosphonates (such as pamidronate among others), gallium nitrate and plicamide, used for the treatment of hypercalcemia may antagonize the effects of Vitamin D. Antiacids based on aluminum salts reduce the absorption of liposoluble vitamins, such as Vitamin D. Barbiturates and anti-seizure drugs may reduce the effect of Vitamin D due to the acceleration of its enzyme-induced hepatic metabolism.
In hypercalcemia therapy, Vitamin D may antagonize the effects of calcitonin if they are given together. The administration of thiazide diuretics and calcium preparations together with Vitamin D may increase the risk of hypercalcemia.
Cholestyramine, cholestipol and/or mineral oils reduce Vitamin D intestinal absorption; therefore, if it is necessary to co-administer them, the dose of Vitamin D must be increased accordingly.
In digitalized patients, the co administration of Vitamin D may cause arrhythmia, in the same way as the co-administration of Vitamin D with phosphate-containing salts may increase the risk of hyperphosphatemia.

Adverse Reactions:
The excessive intake of Vitamin D, either in a single dose or in long-term treatment may lead to severe intoxication. Hypercalcemia induced by Vitamin D chronic administration may cause a generalized vascular calcification, nephrocalcinosis and calcification of other soft tissues, which may result in hypertension and kidney damage. The effects may appear mainly when hypercalcemia is accompanied by hyperphosphatemia.
Vitamin D intoxication may cause death as a result of kidney or vascular damage.
Doses causing toxicity may vary according to each person's sensitivity. The adverse reactions observed more frequently are: constipation (more frequent in children), diarrhea, dry mouth, headache, increased thirst, anorexia, nausea, vomiting, tiredness. In severe cases: bone pain, hypertension, nebulous urine, pruritus, muscle pain, weight loss and/or seizures.

Overdose:
Hypervitaminosis treatment consists in the immediate discontinuation of Vitamin D, low calcium diet, abundant ingestion of liquids, urine acidification during detoxification and support treatment.
Additional therapeutic measures include the administration of citrates, sulphates, phosphates, corticoids, EDTA (ethylenediaminetetraacetic acid) and mithramycin.
In case of accidental overdose and if the patient experiences a hypercalcemic crisis, carry out IV rehydration with physiological saline to increase calcium secretion, and add loop diuretics if necessary.

How supplied: packages containing 1 monodose vial.

Store THE PRODUCT in a dry area, protected from light at 15 to 30°C. This medication must be taken exclusively under prescription and medical supervision.

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

Manufactured at Brobel S.R. L., Cnel. Méndez 438/40, Wilde, Prov. Buenos Aires, for TRB PHARMA S.A., Plaza 939 (1427) Buenos Aires, Argentina. Technical Director: Ma. José Villarraza, Biochemist-Pharmacist. Pharmaceutical product approved by the Ministry of Health. Certificate n.° 55.220

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