



Composition

D-Balance™ 2000 Licap: Each Liquid filled hard gelatin capsule contains Cholecalciferol EP 2000 IU.

D-Balance™ 20000 Licap: Each Liquid filled hard gelatin capsule contains Cholecalciferol EP 20000 IU.

D-Balance™ 40000 Licap: Each Liquid filled hard gelatin capsule contains Cholecalciferol EP 40000 IU.

D-Balance™ 50000 Licap: Each Liquid filled hard gelatin capsule contains Cholecalciferol EP 50000 IU.

Description

D-Balance™ is a preparation of Cholecalciferol, a synthetic form of Vitamin D₃. It is essential for normal bone growth and development and to maintain bone density. Cholecalciferol helps our body to utilize both Calcium and Phosphorus.

Indication and Usage

Prevention and Treatment of Cholecalciferol deficiency states.

Dosage and Administration

Adults: Treatment of Cholecalciferol deficiency: 40,000-50,000 IU/week for 7 weeks, followed by maintenance therapy (1,400-2,000 IU/day). Follow-up 25 (OH)D measurements should be made approximately 3 to 4 months after initiating maintenance therapy to confirm that the target level has been achieved. Prevention of Vitamin D deficiency: 20,000 IU/month.

Children: Treatment of Vitamin D deficiency, 12-18 years: 20,000 IU, once every 2 weeks for 6 weeks. Prevention of Vitamin D deficiency, 12-18 years: 20,000 IU, once every 6 weeks.

Contraindication

- Hypersensitivity to Cholecalciferol or any of the excipients in the product
- Hypervitaminosis D
- Nephrolithiasis
- Diseases or conditions resulting in hypercalcemia and/or hypercalciuria
- Severe renal impairment

Precaution

Cholecalciferol should be used with caution in patients with impairment of renal function and the effect on calcium and phosphate levels should be monitored. Caution is required in patients receiving treatment for cardiovascular disease as the administration of Cholecalciferol may increase the risk of digitalis toxicity (arrhythmia). Cholecalciferol should also be prescribed with caution in patients with sarcoidosis.

There is no clear evidence for causation between Cholecalciferol supplementation and renal stones, but the risk is plausible, especially in the context of concomitant calcium

supplementation. Medical supervision is required whilst on treatment to prevent hypercalcemia.

Drug Interaction

Cholecalciferol is known to interact with Carbamazepine, Dactinomycin, Diuretics, Fosphenytoin, Miconazole, Phenobarbital, Phenytoin, Primidone.

Side Effect

Metabolism and nutrition disorders: Uncommon (a 1/1000 to <1/100): Hypercalcemia and hypercalciuria. Gastrointestinal disorders: Rare (a 1/10,000 to <1/1000): Constipation, flatulence, bloating, abdominal distension, nausea, abdominal pain and diarrhea.

Skin and subcutaneous tissue disorders: Rare (a 1/10,000 to <1/1,000): Pruritus, rash and urticaria.

Use in Pregnancy and Lactation

Studies have shown safe use of doses up to 4000 IU during pregnancy. The recommended daily intake for pregnant women is 400 IU, however, in women who are considered to be Cholecalciferol deficient a higher dose may be required. During pregnancy women should follow the advice of their medical practitioner as their requirements may vary depending on the severity of their disease and their response to treatment.

Cholecalciferol and its metabolites are excreted in breast milk. Overdose in infants induced by nursing mothers has not been observed; however, when prescribing additional Cholecalciferol to a breast-fed child the practitioner should consider the dose of any additional Cholecalciferol given to the mother.

Storage

Store below 30°C, protect from light & moisture. Keep all medicines out of the reach of children.

How supplied

D-Balance™ 2000 Licap: Each Box containing 30 Licap in 30's Alu-Alu blister pack.

D-Balance™ 20000 Licap: Each Box containing 10 Licap in 10's Alu-Alu blister pack.

D-Balance™ 40000 Licap: Each Box containing 10 Licap in 10's Alu-Alu blister pack.

D-Balance™ 50000 Licap: Each Box containing 10 Licap in 10's Alu-Alu blister pack.

Manufactured by



SQUARE
PHARMACEUTICALS LTD.
BANGLADESH