Dcol 1000 IU Drops
(Vitamin D3 (cholecalciferol))

Read all of this leaflet carefully before you start using this Product.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your Doctor or your pharmacist.
- This Product has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your health professional or pharmacist.

In this leaflet:

1. What is Dcol ® and what is it used for?
Dcol is Vitamin D3 (Cholecalciferol) which maintains healthy Calcium and Phosphorus levels in the body for strong bones and increases muscle strength in older adults, and it also plays an active role in a healthy immune response.
Vitamin D3 (Cholecalciferol) is the optimal form of vitamin D.
It is the form of vitamin D that the body synthesizes when the skin is exposed to UV radiation from sunlight (but the ability to do so decreases with age).Cholecalciferol is the most active form of vitamin D that covers the body's need efficiently.
After oral administration, Vitamin D3 is absorbed from the intestine and transported in the blood via protein binding to reach the liver where first hydroxylation occurs and then to the kidney where second hydroxylation occurs.
Vitamin D is stored in reserved compartments such as adipose and muscle tissues.
Its plasma half-life is several days.
Vitamin D3 and its metabolites are excreted mainly in the bile and in faeces with only small amounts appearing in the urine.

Dcol is indicated for:

- Treatment and prevention of vitamin D deficiency status and hypocalcaemia in disorders such as Hypoparathyroidism.
- Treatment of hypoparathyroidism in pregnancy.
- Treatment of osteomalacia and rickets.
- Treatment and prevention of osteoporosis.
- Prevention of Corticosteroid-induced osteoporosis.
- Prevention of fractures.
- Prevention of venous cardiovascular, metabolic disorders including diabetes mellitus, multiple sclerosis and malignant disorders.

2. Before you use Dcol ®
Do not use Dcol if you hypersensitive to any component of Dcol.

Pregnancy and Lactation
Pregnancy:
Hypercalcemia during pregnancy may produce congenital disorders in the offspring, and neonatal Hypoparathyroidism.
However, the risks to the fetus of untreated maternal hypoparathyroidism are considered greater than the risks of hypercalcemia due to vitamin D therapy.
Lactation:
Vitamin D is distributed into breast milk, and its concentration appears to correlate with vitamin D levels in the serum of exclusively breast-fed infants. The use of vitamin D is considered to be usually compatible with breast feeding, although it is recommended that the infant be closely monitored for hypercalcemia or clinical manifestations of vitamin D toxicity if the mother is receiving pharmacological doses of vitamin D.

3. How Should Dcol® to be used?

Your doctor will decide the dosage that you should take in a medical prescription.

Classification	Serum level of 25-hydroxy vitamin D	Dosage regimen	Blood testing
Severe vitamin D deficiency	<10 ng/ml (<25 nmol/L)	**Loading doses:** 50,000 IU (which is equivalent to 1 ml of Dcol 1000 IU) once weekly for 2 to 3 months. -For obese, elderly, patients with malabsorption: 10,000 IU/day (which is equivalent to 10 drops of Dcol 1000 IU) for 8 weeks. **Maintenance doses:** 800 to 2000 IU once daily (which is equivalent to 1 to 2 drops of Dcol 1000 IU) regardless of dosing pattern. -For obese, elderly, patient with malabsorption: 5000 IU/day (which is equivalent 5 drops of Dcol 1000 IU).	-
Vitamin D deficiency	10-15 ng/ml (25-37 nmol/L)	2000-5000 IU once daily (which is equivalent to 2-5 drops of Dcol 1000 IU) Or 5000 IU once daily (which is equivalent to 5 drops of Dcol 1000 IU).	Every 6 months Every 2-3 months
Vitamin D Insufficiency	15-30 ng/ml (37-75 nmol/L)	2000-5000 IU once daily (which is equivalent to 2-5 drops of Dcol 1000 IU) Or 5000 IU once daily (which is equivalent to 5 drops of Dcol 1000 IU).	Every 6 months Every 2-3 months
Supplementation of vitamin D	-	**For Adults:** 1000-2000 IU once daily (which is equivalent to 1-2 drops of Dcol 1000 IU).	-

Precaution:
❖ A special precaution should be taken in:
- Patients with hypercalcemia.
- Infants, who may have increased sensitivity to its effects.
- Patients with renal impairment or calculi, or heart disease, who might be at increased risk of organ damage if hypercalcemia occurred.
- Plasma phosphate concentrations should be controlled during vitamin D therapy to reduce risk of ectopic calcification.
- It is advised that patients receiving pharmacological doses of vitamin D should have their plasma calcium concentration monitored at regular intervals, especially initially or if symptoms suggest toxicity.
- Similar monitoring is recommended in infants if they are breast fed by mothers receiving pharmacological doses of vitamin D.

Drug Interactions
- There is an increased risk of hypercalcemia if vitamin D is given with thiazide diuretics and calcium. Plasma calcium concentrations should be monitored in such situations.
- Some anti-epileptics may increase vitamin D requirements (e.g. Carbamazepine, Phenobarbital, Phenytoin, and Primidone). Rifampicin and Isoniazid may reduce the effectiveness of vitamin D.
- Corticosteroids may counteract the effect of vitamin D.

4. Possible Side Effects
Excessive intake of vitamin D leads to the development of hyperphosphatemia or hypercalcemia. Associated effects of hypercalcemia include hypercalciuria, ectopic calcification, and renal and cardiovascular damage.
Over dosage
Symptoms include: anorexia, lassitude, nausea and vomiting, constipation or diarrhea, polyuria, notarial, sweating, headache, thirst, somnolence and vertigo. Inter-individual tolerance to vitamin D varies considerably; Infants and children are generally more susceptible to its toxic effects.
The vitamin should be withdrawn if toxicity occurs. It has been stated that vitamin D dietary supplementation may be detrimental in persons already receiving an adequate intake through diet and exposure to sunlight, since the difference between therapeutic and toxic concentrations is relatively small.

5. How to Store Dcol
- Keep out of the reach of children.
- Store below 30° C

6. Further Information

6.1 Dcol Contains: Vitamin D3 (Cholecalciferol) as active ingredient, and triglyceride.

6.2 **What Dcol looks like and contents of the pack**
Dcol 1000 IU Drops: Each drop of the oral solution contains 1000 IU of vitamin D3 (Cholecalciferol).

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Philadelphia Pharmaceuticals
King Abdullah II Industrial City / Amman-Jordan

This is a medicament

- Medicament is a product, which affects your health and its consumption contrary to instructions is dangerous for you.

- Follow strictly the doctor`s prescription, the method of use and the instructions of the pharmacist who sold the medicament. The doctor and the pharmacist are the experts in the drugs, their benefits and risks.

- Do not by yourself interrupt the period of the prescribed treatment.

- Do not repeat the same prescription without consulting your doctor.

- Keep all the medicaments out of reach of children.

Council of Arab Health Ministries. Union of Arab Pharmacists