

One Big D-10 000

Vitamin D 10 000IU (Cholecalciferol)



FORMS AND PRESENTATION

One Big D-10 000: Capsules: Box of 30.

COMPOSITION

One Big D-10 000: Each high potency Vitamin D₃ capsule contains:

Vitamin D₃(Cholecalciferol)10000IU.

Excipients: microcrystalline cellulose, lactose, gelatin, titanium dioxide, Azorubine, Quinoline yellow, Patent Blue V.

WHAT One Big D-10 000 IS AND WHAT IT IS TAKEN FOR

Therapeutic class: Vitamins.

ATC code: A11CC05.

Vitamin D₃ is found in the diet and is also produced in the skin after exposure to the sun. Often vitamin D is given in combination with calcium.

One Big D-10 000 may be prescribed by your doctor to treat or prevent vitamin D deficiency. Deficiency of vitamin D may occur when your diet or lifestyle does not provide you enough vitamin D or when your body requires more vitamin D (for instance when you are pregnant). One Big D-10 000 may also be prescribed for certain bone conditions, such as thinning of the bone (osteoporosis) when it will be given to you with other medicines.

BEFORE YOU TAKE One Big D-10 000

Do not take One Big D-10 000 if you:

- Are allergic (hypersensitive) to vitamin D or any of the other ingredients in the capsules.
- Have high levels of vitamin D in your blood (hypervitaminosis D).
- Have high blood levels of calcium (hypercalcaemia) or high urine levels of calcium (hypercalciuria).
- Have kidney stones or serious kidney problems.

Check with your doctor before taking One Big D-10 000 if:

- You have kidney damage or disease. Your doctor may want to measure the levels of calcium in your blood or urine.
- You are being treated for heart disease.
- You have sarcoidosis (an immune system disorder which may affect your liver, lungs, skin or lymph nodes).
- You are already taking additional doses of calcium or vitamin D whilst you are taking One Big D-10 000 your doctor will monitor your blood levels of calcium to make sure they are not too high.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

In particular the following medicines may interact with One Big D-10 000:

- Heart medicines (cardiac glycosides such as digoxin). Your doctor may monitor your heart with an electrocardiogram (ECG) and measure the levels of calcium in your blood.
- Medicines to treat epilepsy (such as phenytoin) or medicines to make you sleep (barbiturates such as phenobarbitone) as these medicines can decrease the effect of vitamin.
- Glucocorticoids (steroid hormones such as hydrocortisone or prednisolone). These can decrease the effect of vitamin D.
- Laxatives (such as paraffin oil) or a cholesterol lowering drug called colestyramine may reduce the absorption of vitamin D.
- Actinomycin (a medicine used to treat some forms of cancer) and imidazole antifungals (medicines such as clotrimazole and ketoconazole used to treat fungal diseases) as they may interfere with the metabolism of vitamin D.

Taking One Big D-10 000 with food and drink

You can take One Big D-10 000 with or without food and drink.

Pregnancy and breast-feeding

If you are pregnant or think you may be pregnant or you are breast-feeding you should talk to your doctor or pharmacist before you take One Big D-10 000.

Driving and using machines

One Big D-10 000 should not affect your ability to drive or operate machinery.

HOW TO TAKE One Big D-10 000

Use only as directed by your physician.

Dosage must be individualized under close medical supervision.

- For Vitamin D resistant rickets: 12 000 – 500 000 IU (0.3 – 12.5 mg) daily.

- For hypoparathyroidism: 50 000 – 200 000 IU (1.5 – 5.0 mg) daily.

The capsules should be swallowed whole (not chewed) with water.

POSSIBLE SIDE EFFECTS

Like all medicines, One Big D-10 000 can cause side effects, although not everybody gets them.

Side effects with One Big D-10 000 may include:

Uncommon side effects (affecting less than 1 in 100 people):

- Too much calcium in your blood (hypercalcemia). You may feel or be sick, lose your appetite, have constipation, stomach ache, feel very thirsty, have muscle weakness, drowsiness or confusion.

- Too much calcium in your urine (hypercalciuria).

Rare side effects (affecting less than 1 in 1000 people):

- Skin rash

- Itching

- Hives

Tell your doctor or pharmacist if any of the side effects become serious or if you notice any side effects not listed.

HOW TO STORE One Big D-10 000

Store below 30°C.

Keep in original pack in intact conditions.

Date of revision: June 2018

This is a medicament

- A 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 experts in medicine, its benefits and risks
- Do not by yourself interrupt the period of treatment prescribed for you
- Do not repeat the same prescription without consulting your doctor
- Medicament: keep out of reach of children

Council of Arab Health Ministers
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Benta S.A.L.
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