

Maxi-D 10,000 I.U.

Vitamin D3 (Cholecalciferol)

Forms and presentation

Maxi-D 10,000 I.U. hard capsules
Box of 30 capsules

Qualitative and quantitative composition

Each capsule contains 10,000 International Units of Vitamin D3 (Cholecalciferol)

Excipients: starch sodium octenyl succinate, arabic gum, DL- α -tocopherol, sodium ascorbate, tricalcium phosphate, edible vegetable oil, maltodextrin, microcrystalline cellulose, lactose anhydrous, azorubine, brilliant blue, titanium dioxide, quinoline yellow, gelatin.

What is Maxi-D 10,000 I.U.

Maxi-D 10,000 I.U. contains the active ingredient cholecalciferol, also known as vitamin D3.

Therapeutic class: vitamins
ATC code: A11CC05

What is Vitamin D3 used for

Vitamin D3 is needed to maintain normal levels of calcium and phosphorus. In its biologically active form, vitamin D3 stimulates intestinal calcium absorption, incorporation of calcium into the bones, and release of calcium from bone tissue. It also stimulates the active and passive transport of phosphate. In the kidneys, vitamin D3 inhibits the excretion of calcium and phosphate by promoting tubular resorption.

Maxi-D 10,000 I.U. indications

- Treatment and prevention of vitamin D deficiency
 - Certain bone conditions such as osteoporosis
- This medicine is used alone or in combination with calcium.

Contraindications

- Do not take Maxi-D 10,000 I.U. in case of:
- Allergy (hypersensitivity) to vitamin D or any of the excipients
 - High levels of vitamin D in your blood (hypervitaminosis D)
 - High blood levels of calcium (hypercalcaemia) or high urine levels of calcium (hypercalciuria)
 - Kidney stones or serious kidney problems

Warnings and precautions

- Check with your doctor before taking Maxi-D 10,000 I.U. if:
- You have kidney damage or disease.
 - You are being treated for heart disease.
 - You are suffering from an immune disorder, such as sarcoidosis.
 - You have elevated levels of phosphate in the blood (hyperphosphatemia).
 - You are already taking additional doses of calcium or vitamin D. Your doctor will monitor your blood calcium levels to make sure they are within normal limits.

Possible interactions with other medications

- Please tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines, including medicines obtained without a prescription. In particular:
- Heart medicines (cardiac glycosides, such as digoxin). Your ECG and serum calcium levels need to be monitored
 - Anti-epileptic medications (such as phenytoin) or medicines to make you sleep (barbiturates) as these can decrease the effect of vitamin D
 - Glucocorticoids (such as hydrocortisone or prednisone) can decrease the effect of vitamin D
 - Laxatives (such as paraffin oil), cholestyramine and colestipol (medicines used to lower high cholesterol levels in the blood), and orlistat (medicine used to treat obesity) can decrease the absorption of vitamin D
 - Actinomycin (an anticancer medicine) and imidazole antifungals (such as ketoconazole and clotrimazole) can interfere with the metabolism of vitamin D
 - Other medicines containing calcium, vitamin D or its analogues and thiazide diuretics as they may increase the level of calcium in your blood.

Pregnancy and breastfeeding

If you are pregnant or plan on getting pregnant or you are breast-feeding, you should talk to your doctor or pharmacist before taking Maxi-D 10,000 I.U.

Driving and operating machinery

Maxi-D 10,000 I.U. has no influence on your ability to drive or operate machinery.

How to take Maxi-D 10,000 I.U.

Use this medicine only as directed by your physician. Dose and duration of treatment depend on your age and severity of deficiency.

For optimal absorption, Maxi-D 10,000 I.U. should be taken with the largest meal of the day.

In case of difficulty swallowing (children or elderly), the capsule can be opened and emptied into any food or drink.

Use in adults:

- Prevention of vitamin D deficiency: 1 capsule per week
- Treatment of vitamin D deficiency: depending on serum vitamin D levels, refer to the table below:

Serum 25(OH)D level	Dose
Less than 10 ng/ml (25nmol/L)	1 capsule daily for 12 weeks
10 - 15 ng/ml (25 - 37 nmol/L)	1 capsule 3 times per week
15 - 20 ng/ml (37 - 50 nmol/L)	1 capsule 2 times per week
20 - 30 ng/ml (50 - 75 nmol/L)	1 capsule per week

- Maintenance treatment (after a normal level higher than 30 ng/ml (75 nmol/L) is achieved): 1 capsule per week

Use in children:

- Prevention of vitamin D deficiency: 1 capsule per week
- Treatment of vitamin D deficiency: 1 capsule per day for a duration specified by your doctor

Possible side effects:

Side effects of Maxi-D 10,000 I.U. may include:

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

- Hypercalcaemia (high blood calcium level): symptoms include loss of appetite, constipation, stomach ache, intense thirst, muscle weakness, drowsiness, and confusion.
- Hypercalciuria (high urine calcium level)

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

- Skin rash
- Itching
- Hives

Inform your doctor or pharmacist if you feel any of the side effects listed above or if you notice any other unlisted adverse events.

How to store Maxi-D 10,000 I.U.

- Keep this medicine out of sight and reach of children
- Store in a cool and dry location, below 25°C, and away from direct sunlight.
- Do not use this medicine after the expiry date stated on the blister and outside carton.

Date of Revision: April 2022.

MARKETING AUTHORIZATION HOLDER AND MANUFACTURER

Benta S.A.L.
Dbayeh - Lebanon

