

Bio-D3

Vitamin D₃ (Cholecalciferol)

Read this entire leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine 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 you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet?

1. What Bio-D3 is and what it is used for
2. What you need to know before you use Bio-D3
3. How to use Bio-D3
4. Possible side effects
5. How to store Bio-D3
6. Contents of the pack and other information

1. What Bio-D3 is and what it is used for

Bio-D3 contains colecalciferol (vitamin D₃). Vitamin D₃ can be found in some foods and is also produced by the body when skin is exposed to sunlight. Vitamin D₃ helps the kidneys and intestine absorb calcium and it helps build bones.

Bio-D3 is used

- To prevent vitamin D deficiency when there is a significant risk of deficiency or an increased demand for vitamin D.
- With other medicine to treat certain bone conditions, such as thinning of the bone (osteoporosis).
- To treat vitamin D deficiency that has been confirmed by laboratory tests.

2. What you need to know before you use Bio-D3

Do not take Bio-D3:

- If you are allergic to vitamin D₃ or any of the other ingredients of this medicine (listed in section 6);
- If you have high levels of calcium in your blood (hypercalcaemia) or urine (hypercalciuria);
- If you have kidney stones (renal calculi);
- If you have serious renal impairment;
- If you have high levels of vitamin D₃ in your blood (hypervitaminosis D);
- If you have pseudohypoparathyroidism (disturbed parathyroid hormone metabolism);
- If you are pregnant.

If any of the above applies to you, talk to your doctor or pharmacist before taking Bio-D3.

Warnings and precautions

Talk to your doctor or pharmacist before taking Bio-D3 if you:

- Are undergoing treatment with certain medicines used to treat heart disorders (e.g. cardiac glycosides, such as digoxin);
- Have sarcoidosis (an immune system disorder which may cause increased levels of vitamin D₃ in the body);
- Are taking medicines containing vitamin D₃, or eating foods or milk enriched with vitamin D₃;
- Are likely to be exposed to a lot of sunshine whilst using Bio-D3;
- Take additional supplements containing calcium. Your doctor will monitor your blood levels of calcium to make sure they are not too high whilst you are using Bio-D3;
- Have kidney damage or disease. Your doctor may want to measure the levels of calcium in your blood or urine.

Children

This medicine is not suitable for use in children and adolescents under 10 years of age.

Other medicines and Bio-D3:

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. This is especially important if you are taking:

- Medicines that act on the heart or kidneys, such as cardiac glycosides (e.g., digoxin) or diuretics (e.g., bendroflumethazide). When used at the same time as vitamin D₃ these medicines may cause a large increase in the level of calcium in the blood and urine;
- Medicines containing vitamin D₃ or eating food rich in vitamin D₃, such as, some types of vitamin D₃-enriched milk;
- Actinomycin (a medicine used to treat some forms of cancer) and imidazole antifungals (e.g., clotrimazole and ketoconazole, medicines used to treat fungal disease). These medicines may interfere with the way your body process vitamin D₃;
- The following medicines because they can interfere with the effect or the absorption of vitamin D₃:
 - Antiepileptic medicines (anticonvulsants), barbiturates;
 - Glucocorticoids (steroid hormones such as hydrocortisone or prednisolone). These can decrease the effect of vitamin D₃;
 - Medicines that lower the level of cholesterol in the blood (such as cholestyramine, or colestipol);
 - Certain medicines for weight loss that reduce the amount of fat your body absorbs (e.g. orlistat);
 - Certain laxatives (such as liquid paraffin).

Bio-D3 with food and drink

See section 3 “How to take Bio-D3”

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

This high strength formulation is not recommended for use in pregnant and breastfeeding women.

Driving and using machines

There is limited information on the possible effects of this medicine on your ability to drive. However, it is not expected that it would affect your ability to drive or to operate machinery.

3. How to take Bio-D3

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The capsules should be swallowed whole with water.

You should take Bio-D3 preferably together with a large meal to help your body absorb the vitamin D.

Use in children and adolescents

The recommended dose for:

- Prevention of deficiency 10-18 years: 25,000 IU (1 capsule of Bio-D3) every 6 weeks
- Treatment of deficiency 10-18 years: 25,000 IU (1 capsule of Bio-D3) once every 2 weeks for 6 weeks (followed by maintenance therapy of 400 IU – 1,000 IU/day, such as 1 capsule a month).

Use in pregnancy and breast-feeding

This high strength formulation is not recommended

Use in adults

The recommended dose for:

- Prevention of vitamin D deficiency: 25,000 IU/month (1 capsule of Bio-D3)
- Addition to specific therapy for osteoporosis: 25,000 IU/month (1 capsule of Bio-D3)
- Treatment of vitamin D deficiency: 50,000 IU/week (2 capsules of Bio-D3) for 6-8 weeks, followed by maintenance therapy (1,400- 2,000 IU/day, such as 2 capsules a month).

If you take more Bio-D3 than you should

If you or your child take more medicine than prescribed, stop using this medicine and contact your doctor. If it is not possible to talk to a doctor go to the nearest hospital emergency department and take the medicine package with you. The most common symptoms of overdose are: nausea, vomiting, excessive thirst, the production of large amounts of urine over 24 hours, constipation and dehydration., high levels of calcium in the blood (hypercalcaemia and hypercalciuria) shown by lab test.

If you forget to take Bio-D3

If you forget to take a dose of Bio-D3, take the forgotten dose as soon as possible. Then take the next dose at the correct time. However, if it is almost time to take the next dose, do not take the dose you have missed; just take the next dose as normal.

Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Possible side effects may include:

Uncommon (may affect up to 1 in 100 people)

- High level of calcium in your blood (hypercalcaemia)
- High level of calcium in your urine (hypercalciuria)

Rare (may affect up to 1 in 1,000 people)

- Skin rash
- Itching
- Hives

5. How to store Bio-D3

Store below 25°C, away from moisture, heat and light.

Keep in original pack in intact conditions.

6. Contents of the pack and other information

Bio-D3: Capsules; Box of 15 or 30.

Each capsule contains Vitamin D3 25,000IU.

Excipients: Maize oil, tunic: gelatin, solvent: glycerol.

Date of revision: June 2019.

Manufactured by Lambo Laboratoria NV, Belgium for Benta S.A.L., - Lebanon on behalf of Laboratoire Surveil - Belgium.

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
Union of Arab Pharmacists

**Benta S.A.L.
Dbayeh - Lebanon**