

PACKAGE LEAFLET: Information for the patient

VITAMINA D3

Oral drops, solution – 14 400 I.U. / ml

Cholecalciferol (Vitamin D3)

Read all of this 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 only. Do not pass it on to others. It may harm them, even if their signs of illness 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 doctor or pharmacist.

In this leaflet:

1. What Vitamina D3 is and what it is used for
2. Before you take Vitamina D3
3. How to take Vitamina D3
4. Possible side effects
5. How to store Vitamina D3
6. Further information

1. WHAT VITAMINA D3 IS AND WHAT IT IS USED FOR

Vitamina D3 oral drops, solution contains the active substance cholecalciferol (vitamin D3).

Vitamina D3 is used:

- for prevention and treatment of vitamin D deficiency;
- for treatment of rickets (a condition that affects bone development in children);
- as an adjunct to osteoporosis treatment of patients who are at risk of vitamin D deficiency.

2. BEFORE YOU TAKE VITAMINA D3

Do not take Vitamina D3 14 400 I.U./ml oral drops, solution:

- if you are allergic to cholecalciferol or to any of the other ingredients of this medicine, listed in section 6;
- if you suffer from medical conditions that result in a high calcium level in the blood or increased calcium excretion in the urine [as with treatment with certain medications (benzothiadiazine derivatives) or if you are bedridden];
- if you suffer or have a tendency to suffer from calcium-containing kidney stones;
- if you suffer from an excess of vitamin D;
- if you have severe arteriosclerosis (hardening of the arteries);
- if you suffer from severe kidney dysfunction.

Warnings and precautions

Talk to your doctor or pharmacist before taking Vitamina D3.

Special care when taking Vitamina D3 is required:

- if you are being treated with certain heart drugs (cardiac glycosides) or thiazide-type diuretic drugs;
- if you suffer from kidney dysfunction. Your doctor will monitor the calcium and phosphate levels in the blood in this case. The risk of soft tissue calcification has to be considered;
- in severe kidney dysfunction, cholecalciferol is not utilized. Your doctor will possibly recommend another vitamin D supplement;
- if you suffer from sarcoidosis (Boeck's disease), there is a risk of increased formation of the active form of vitamin D;
- in case of reduced bone mass due to inactivity (e.g. bedrest) there is an increased risk of occurrence of elevated calcium levels in the blood.

During long-term use, your doctor will check the levels of calcium in your blood and urine regularly and monitor your kidney function. If necessary, your doctor may tell you to reduce the dose or stop the treatment.

Raised parathyroid hormone levels can enhance vitamin D metabolism and this increases vitamin D requirement.

Additional doses of vitamin D should only be taken under close medical supervision.

Children and adolescents

Avoid the use of other vitamin D-containing products, especially in infants. If in doubt, your doctor will decide about the additional use of vitamin-enriched foods or baby foods and vitamin D-containing medicines.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken other medicines, including those taken without a prescription. This is especially important if you are taking:

- Rifampicin or isoniazid (against tuberculosis);
- Certain heart medicines (cardiac glycosides): they may enhance their harmful effects by increasing the blood calcium levels (risk of arrhythmias). Strict medical supervision is required, possibly including electrocardiogram (ECG) examination and control of the calcium level in the blood;
- Thiazide diuretics: they increase the risk for the occurrence of elevated calcium levels in the blood because these drugs reduce the urinary excretion of calcium. Your doctor will check your blood calcium levels regularly in this case;
- Medicines for the treatment of epilepsy (carbamazepine, phenobarbital, phenytoin, primidone) or certain hormones of the adrenal cortex (glucocorticoids, “cortisone”): they may increase your vitamin D requirement;
- Medicines to lower blood lipids (e.g. orlistat, cholestyramine, colestipol): they may reduce the absorption of vitamin D through the intestines;
- Medicines containing magnesium (e.g. antacids): they should not be used concomitantly as this may lead to high levels of magnesium in the blood (hypermagnesaemia);
- Aluminium-containing pills (against heartburn).

Using Vitamina D3 with food and drinks

Caution is advised when taking foods with high calcium content, vitamin-enriched food or infant formula.

You should take this medicine preferably together with a large meal to help your body absorb the vitamin D3. You can also mix the drops with cold or lukewarm food, to help you take this medicine.

Pregnancy and breastfeeding

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

Pregnancy

If your doctor prescribes Vitamina D3 when you are pregnant, be careful to keep strictly to the dose your doctor has prescribed, since overdose of vitamin D3 may involve a risk of physical and mental retardation, as well as heart and eye diseases of your child.

Breastfeeding

Vitamin D and its metabolites pass into in breast milk.

Overdose in infants induced by nursing has not been observed. This fact, however, should be taken into account if the child receives additional vitamin D.

Driving and using machines

There are no known effects on the ability to drive and use machines.

3. HOW TO TAKE VITAMINA 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 dosage will be determined by your doctor. The dose depends on the condition for which you get Vitamina D3. Therefore, always take the dose that has been prescribed individually for you, even if you know someone else who has been prescribed a much higher dose.

Unless otherwise prescribed by your doctor, the recommended dose is:

Prevention of vitamin D deficiency:

The usual daily dose is:

For newborns, infants and children from the second week of life to the age of 3 years: 1 - 2 drops.

For children aged 4 years and above and adolescents: 1 - 3 drops.

For adults aged 19 to 70 years: 1 - 4 drops.

For elderly people aged above 70 years: 2 - 4 drops.

Treatment of rickets

The total amount of required vitamin D depends on the severity of the disease.

In existing rickets, treatment is started with a preparation with a higher concentration of vitamin D for the initial treatment.

Subsequently, the usual dose is 2 - 12 drops of Vitamina D3 daily.

Treatment of vitamin D deficiency

The usual daily dose is:

For children and adolescents: 5 drops daily for 6 weeks, then 1 - 3 drops daily.

For adults aged 19 to 70 years and elderly people aged above 70 years: 15 drops daily for 8 weeks, then 3 - 5 drops daily.

Adjunct to osteoporosis treatment of patients who are at risk of vitamin D deficiency

The usual daily dose is:

For adults aged 19 years and above: 2 - 4 drops daily or 14 - 26 drops weekly.

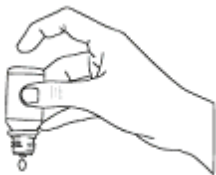
Method of administration

Vitamina D3 drops are taken directly orally. The best way is to drip them straight into the mouth or, if necessary, administer with a spoon and some liquid.

Please talk to your doctor or pharmacist if you have the impression that the effect of Vitamina D3 is too strong or too weak.

Instructions for use

For withdrawal, hold the bottle vertically and gently tap the bottom of the bottle with your finger until the first drop appears.



If you take more Vitamina D3 than you should

In case of overdose with Vitamina D3 drops you should contact a doctor.

Symptoms of overdose may include: headache, loss of appetite, weakness, weight loss, disorders of the gastrointestinal tract (feeling sick, vomiting, constipation), growth disorders, increased urine volume, increased fluid intake, signs of paralysis, feebleness, increased blood pressure and in severe cases irregular heart beat.

The doctor decides on the severity of poisoning and determines the required treatment.

If you forget to take Vitamina D3

Do not use a double dose (or higher) to make up for a forgotten dose.

If you stop taking Vitamina D3 oral drops

There are no known withdrawal symptoms.

If you have 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.

Vitamin D may cause the following side effects, especially in overdose:

- Immune system disorders: hypersensitivity reactions;
- Metabolism and nutrition disorders: weakness, loss of appetite (anorexia), thirst, increased calcium in blood and urine (hypercalcemia, hypercalcuria);
- Psychiatric disorders: drowsiness, confusion;

- Nervous system disorders: headache;
- Gastrointestinal disorders: constipation, flatulence, nausea, stomach pain, diarrhea, vomiting, metallic taste, dry mouth;
- Skin and subcutaneous tissue disorders: rash, pruritus;
- Renal and urinary disorders: excessive build-up of calcium in the kidneys (nephrocalcinosis), increased quantity of urine excreted (polyuria), intense thirst (polydipsia), kidney disease (renal insufficiency).

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE VITAMINA D3

Keep out of the reach and sight of children!

Do not store above 25°C!

Store in the original package in order to protect from light.

Do not use this medicine after the expiry date which is stated on the package.

6. FURTHER INFORMATION

What Vitamina D3 14 400 I.U./ml oral drops, solution contains

The active substance is cholecalciferol (vitamin D3).

1 ml (= 36 drops) contains 14 400 I.U. cholecalciferol, therefore 1 drop = 400 I.U. cholecalciferol.

The other ingredients of the solution are: α -tocopherol acetate, citrus limonium essential oil, and refined olive oil.

Content of the pack

Amber glass bottles of 12.5 ml.

Marketing Authorisation Holder (MAH) and Manufacturer

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Tirana, Albania.

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