

PACKAGE LEAFLET: Information for the patient

VITAMINA D3

Oral drops, solution – 10 000 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
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1. WHAT VITAMINA D3 IS AND WHAT IT IS USED FOR

Vitamina D3 oral drops, solution contains cholecalciferol (vitamin D3) which is involved in bone fixation of calcium.

This medicinal product is indicated for the prevention and treatment of vitamin D deficiency.

2. BEFORE YOU TAKE VITAMINA D3

Do not take Vitamina D3 10 000 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 have high calcium levels in the blood (hypercalcaemia) or in the urine (hypercalciuria);
- if you have kidney stones (nephrolithiasis) or calcium deposits in the kidneys (nephrocalcinosis);
- if you have a kidney disease (renal insufficiency) (see section “Warnings and precautions”).

Warnings and precautions

Your doctor might recommend taking Vitamina D3 as prevention against vitamin D deficiency:

- for neonates (especially preterm babies) and infants;
- during the last trimester of pregnancy;
- for breastfeeding women, in winter and in spring;
- for the elderly;
- in case of inadequate exposure to sunlight, particularly in the child and the adolescent;
- in case of an unbalanced diet (e.g., poor in calcium, vegetarian diet);
- in case of intense skin colouration;
- in case of extensive skin diseases, infectious diseases (e.g., tuberculosis, leprosy), digestive diseases or liver diseases (hepatic insufficiency);
- in patients under treatment with antiepileptic medicines or under long-term therapy with certain anti-inflammatory agents.

Please talk to your doctor or pharmacist before taking Vitamina D3, if any of the following applies to you. Your doctor might prescribe regular tests to check the levels of vitamin D or calcium in blood and urine in the following cases:

- if you have to take Vitamina D3 for a prolonged period and at high doses,
- if you are elderly and already under treatment with medicines for certain heart diseases (cardiac glycosides) or with medicines that reduce blood pressure by increasing the production of urine (diuretics);

- if you have sarcoidosis (Boeck's disease), an inflammatory disease that can involve the entire body and lead to the formation of nodules. If your levels of vitamin D or calcium are high, your doctor will reduce the dose or interrupt treatment with Vitamina D3.
- If you have scarce kidney function, you should not take Vitamina D3, but if the doctor deems that treatment with Vitamina D3 is absolutely necessary, you will need to perform regular tests to check blood levels of calcium and phosphate. If your calcium and phosphate levels are high, your doctor will reduce the dose or interrupt treatment with Vitamina D3.

Inform the doctor in the following cases because it might be necessary to increase the doses, compared to the one indicated in section 3 “How to take Vitamina D3”:

- if you are taking medicines that are used to treat seizures (anticonvulsants or barbiturates) (see section “Taking other medicines”)
- if you are taking cortisone, medicines that are used to treat inflammation (see section “Taking other medicines”)
- if you are taking medicines that are used to reduce the presence of fatty acids in the blood, such as cholestipol, cholestyramine and orlistat (see section “Taking other medicines”)
- if you are taking antacids that contain aluminium, medicines that are used to treat the excessive presence of acid in the stomach, which can even enter the oesophagus (see section “Taking other medicines”);
- if you are obese;
- if you have digestive diseases (intestinal malabsorption, mucoviscidosis or cystic fibrosis);
- if you have a liver disease (hepatic insufficiency).

Taking other medicines

Please contact your doctor or pharmacist if you are taking or have recently taken other drugs, including those taken without a prescription.

Particularly, tell your doctor if you are taking the following medicines because they might reduce the effect of Vitamina D3:

- medicines that are used to treat seizures (anticonvulsants or barbiturates);
- medicines that are used to reduce the presence of fatty acids in the blood, such as cholestipol, cholestyramine and orlistat;

- if you are taking antacids that contain aluminium, medicines that are used to treat the excessive presence of acid in the stomach, which can even enter the oesophagus;
- cortisone, medicines that are used to treat inflammation.

Moreover, tell your doctor if you are taking the following medicines. Your doctor will monitor your condition and carefully evaluate whether you need to perform additional tests:

- thiazide diuretics, medicines that are used to treat high blood pressure by increasing the production of urine;
- digitalis, medicine that is used to treat certain heart diseases;
- preparations that contain magnesium;
- warfarin, medicine that is used to make blood more fluid.

Taking Vitamina D3 with food and drinks

Tell your doctor if you are taking other products that already contain vitamin D, foods fortified with vitamin D or if you use milk enriched with vitamin D so that they might consider the total dose of vitamin D.

The intake of high amounts of alcohol for a very long time (chronic alcoholism) reduces vitamin D reserves in the liver.

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

During the first 6 months of pregnancy, the doctor will prescribe this medicine only if they deem it strictly necessary, due to the risk of harmful effects for the foetus. (See Section 3 “If you take more Vitamina D3 than you should”).

Breastfeeding

Vitamin D and its metabolites are excreted in breast milk.

Your doctor will prescribe this medicine during breastfeeding, when necessary. This does not substitute the administration of vitamin D to the neonate.

Driving and using machines

It is unlikely that Vitamina D3 will have any effects on the ability to drive vehicles or 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 doses and duration of treatment will be assessed by your doctor based on your health condition. Do not exceed the doses indicated by your doctor.

The doses must be taken orally. You are recommended to take Vitamina D3 with meals.

The daily doses indicated below can even be taken once a week by multiplying the indicated daily dose by seven.

One drop of Vitamina D3 10 000 I.U./ml contains 300 I.U. of cholecalciferol.

Neonates, children and adolescents (<18 years).

Prevention: the recommended dose is 2 - 4 drops a day (equivalent to 600 – 1 200 I.U. of vitamin D3).

Treatment: the recommended dose is 8 - 16 drops a day (equivalent to 2 400 – 4 800 I.U. of vitamin D3) for 4 - 5 months.

Pregnant women

The recommended dose is 3 - 4 drops a day (equivalent to 900 – 1 200 I.U. of vitamin D3) during the last trimester.

Adults and the elderly

Prevention: the recommended dose is 3 - 4 drops a day (equivalent to 900 – 1 200 I.U. of vitamin D3).

In case of a high risk of deficiency, your doctor will assess whether you need to increase the dose to 8 drops a day (equivalent to 2 400 I.U. of vitamin D3).

Treatment: the recommended dose is 20 - 40 drops a day (equivalent to 6,000 – 12 000 I.U. of vitamin D3) for 1 - 2 months.

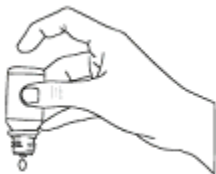
Method of administration

Vitamina D3 drops are taken directly orally. It can be taken on its own or you can mix the prescribed number of drops with a small amount of cold or lukewarm food immediately before use. Make sure the entire dose is taken.

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

To take the drops, hold the bottle vertically and gently tap the bottom of the bottle with your finger until the first drop comes out.



If you take more Vitamina D3 than you should

In case of accidental ingestion/intake of an overdose of Vitamina D3, immediately inform the doctor or visit the closest hospital. In case of overdose, there might be an increase in the levels of calcium in blood and urine, with the following symptoms: nausea, vomiting, thirst, intense thirst (polydipsia), increased quantity of urine excreted (polyuria), constipation and dehydration.

Chronic overdose can cause build-up of calcium salts in blood vessels and organs.

The use of an excessive dose of vitamin D during the first 6 months of pregnancy can cause serious harm to the fetus and to the neonate.

If you forget to take Vitamina D3

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

If you stop taking Vitamina D3 oral drops

There are no known withdrawal symptoms.

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.

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 10 000 I.U./ml oral drops, solution contains

The active substance is cholecalciferol (vitamin D3).

1 ml (~ 33 drops) contains 10 000 I.U. cholecalciferol, therefore 1 drop = 300 I.U.

cholecalciferol.

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

Contents of the packaging

Amber glass bottle of 12.5 ml.

Marketing Authorisation Holder (MAH) and Manufacturer

PROFARMA sh.a.,

St. "Skënder Vila",

Tirana, Albania.

Tel.: + 355 4 23 89 602

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