PACKAGE LEAFLET: Information for the user

VITAMINA D3

Solution for oral use or I.M. injection – 200.000 I.U/ml or 300.000 I.U/ml

Cholecalciferol (vitamin D3)

Read all of this leaflet carefully before you start using 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

Vitamina D3 ampoules contain cholecalciferol (vitamin D3) which is involved in bone fixation of calcium.

This medicinal product is indicated in vitamin D deficiency or insufficiency, prevention and treatment of vitamin D deficiency associated with malabsorption in gastrointestinal tract, treatment of rickets (a bone disease caused by vitamin D deficiency), osteomalacia (a bone disease due to decreased bone mineral), supportive treatment of bone loss (osteoporosis), supportive treatment in cases in which increased risk of osteoporotic fractures and treatment of

hyperparathyroidism (a disease due to developing a parathormone - a hormone that regulates metabolism of calcium in the body - gland tumor).

2. BEFORE YOU USE VITAMINA D3

Vitamina D3 ampoules must not be taken:

- if you are allergic to cholecalciferol (vitamin D3) or to the excipient of this medicine, mentioned in section 6,
- if you suffer from medical conditions that result in high calcium level in the blood or increased calcium excretion in the urine, such as 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 have severe high blood pressure, severe arterial stiffness and active pulmonary tuberculosis, you should not use high doses of this medicine for a long period of time,
- if you suffer from D hypervitaminosis (a disease caused by excessive intake or accumulation of vitamin D).

Warnings and precautions

Please talk to your doctor or pharmacist before taking Vitamina D3, if any of the following applies to you:

- If you have to use vitamin D3 for long-term treatment, your kidney functions should be monitored,
- If you are taking another drug containing vitamin D and its derivates,
- The daily dose of vitamin D is 600 I.U. The tolerable maximum daily dose is 4000 I.U. In pregnant or breastfeeding women, if required, it can be used at a proper dose according to doctor’s advice.

If these warnings apply to you even for a period of time in the past, please consult your doctor.

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. Do not forget to inform your doctor for the

treatment with Vitamina D3 if you have been given another drug during the treatment.

This is especially important if you are taking:

- Certain heart medicines (cardiac glycosides): they may enhance their harmful effects by increasing the blood calcium levels (risk of arrhythmias). A 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 tuberculosis (rifampicin, isoniazid), 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 and cholestyramine): 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).
- Medicines used in treating hypercalcaemia (calcitonin, etidronate, gallium nitrate, pamidronate or plicamycin): vitamin D may antagonize them when used concomitantly.

Concurrent use of Vitamina D3 with other drugs containing vitamin D or its derivates is not recommended because of increased potential for toxicity.

Using Vitamina D3 with food and drinks

It does not have any known interactions with food and drink.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, or if you suspect you may be pregnant or intend to get pregnant, ask your doctor or pharmacist for advice before taking this medicine.

This medicinal product should not be used during pregnancy or breastfeeding unless it is necessary.

Driving and using machines

No specific data is available on its effects on the ability to drive and use machines.

Important information about the excipient of Vitamina D3

Warning is not required for the excipient used in the composition of this medicinal product.

3. HOW TO USE VITAMINA D3

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

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

Vitamina D3 200.000 I.U/ml:

Prevention of vitamin D deficiency:

- Infants receiving vitamin D enriched milk: ½ ampoule (100.000 I.U) every 6 months.
- Nursed infants or infants not receiving vitamin D enriched milk or young children up to 5 years of age: 1 ampoule (200.000 I.U) every 6 months.
- Adolescents: 1 ampoule (200.000 I.U) every 6 months during winter.
- Pregnancy: ½ ampoule (100.000 I.U) from 6^{th} or 7^{th} month of pregnancy.
- Elderly: ½ ampoule (100.000 I.U) every 3 months.

Vitamin D deficiency:

1 ampoule which can be renewed once 1 to 6 months later.

Vitamina D3 300.000 I.U/ml:

For the treatment of vitamin D deficiency or insufficiency and treatment of rickets in newborns, infants and children it is generally given as 1 ml (300.000 I.U) at 3-4 week-intervals and for prophylaxis and treatment of vitamin D deficiency in malabsorption it is given as 1 ml (300.000 I.U) or as 2 doses of ½ ml at 3-4 week-intervals.

For the treatment of osteomalacia caused by decreased bone mineral, supportive treatment in bone loss, prophylaxis in patients increased risk of osteoporotic fractures and treatment of

hyperparathyroidism, 1 ml (300.000 I.U) is given once weekly for 6-12 weeks.

Dose and duration of treatment are determined on doctor's advice according to the disease to be treated. Your doctor will tell you how frequently you will use Vitamina D3. Depending on your response to treatment, your doctor may recommend a higher or lower dose. Do not exceed the recommended dose.

This medicine has been prescribed to you personally for a particular condition:

- it can not be adapted for another condition.
- do not recommend it to another person.

Method of administration

Vitamina D3 ampoules can be administered via oral or intramuscular route; however, it must be injected into the muscle in calcium malabsorption.

If you use more Vitamina D3 than you should

Headaches, fatigue, loss of appetite, weight loss, depression, growth disorders, nausea, vomiting, constipation, excessive production of urine, intense thirst, dehydration, high bloood pressure, kidney stones, tissue calcificatios (in particular renal and vascular calcium deposits), failure of kidney function, heart rhythm disorder or even coma may be signs of excessive vitamin D intake. The biological signs of vitamin D overdose are increased calcium and phosporous levels in the blood and in the urine, low concentration of parathyroid hormone and high concentration of 25-hydroxyvitamin D.

In case of overdose, the treatment should be stopped. Decrease calcium intake (e.g. dairy products) and abundant drinking.

If you forget to take Vitamina D3

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

If you stop taking Vitamina D3

There are no known withdrawal symptoms.

Do not stop your treatment with Vitamina D3 unless your doctor tells you to do so.
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. Cholecalciferol (vitamin D3) may cause the following side effects, especially in overdose:

- **Metabolic and nutritional disorders:** Increased calcium in blood and urine (hypercalcemia, hypercalcuria)
- **Gastrointestinal disorders:** Constipation, flatulence, nausea, stomach pain, diarrhea.

Common (can affect up to 1 in 10 people):

If administered by injection, injection site reactions such as pain, itching, infection, granuloma (a granular mass to the touch), panniculitis (inflammation of the subcutaneous fattty tissue), redness, nodule (a small ball of varying hardness that develops in or under the skin) or urticaria (a skin reaction that feels like a nettle sting) may occur.

Very rare (can affect up to 1 in 10 000 people):

Hypersensititvity reaction (allergy), hypercalcaemia (abnormally high blood calcium levels), hypercalciuria (excessive urinary elimination of calcium), calcium lithiasis (kidney stones).
These adverse reactions may occur especially in the case of overdose. If you notice side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. HOW TO STORE VITAMINA D3

Keep out of the reach and sight of children!
Do not store above 25°C!
Do not use this medicine after the expiry date which is stated on the package!

6. FURTHER INFORMATION

What Vitamina D3 solution for oral use or I.M. injection contains:

The active substance is cholecalciferol (vitamin D3).

The excipient of the solution is ethyl oleate.

Content of the pack

Carton box which contains one amber glass ampoule of 1 ml.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

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This leaflet was formulated in August 2023.