

Package leaflet: Information for the patient

Cholecalciferol Alfrapharma 20.000 IE zachte capsules

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Cholecalciferol (vitamin D₃)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 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 <Cholecalciferol soft capsules> is and what it is used for
2. What you need to know before you take <Cholecalciferol soft capsules>
3. How to take <Cholecalciferol soft capsules>
4. Possible side effects
5. How to store <Cholecalciferol soft capsules>
6. Contents of the pack and other information.

1. What <Cholecalciferol soft capsules> is and what it is used for

<Cholecalciferol soft capsules> contains the active substance Cholecalciferol, better known as Vitamin D₃.

<Cholecalciferol soft capsules> is indicated for:

- treatment of vitamin D deficiency in adults.
- Prevention of Vitamin D deficiency in adults with an identified risk when therapeutic adherence (or compliance) is not achieved by daily administration of low cholecalciferol doses.

You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you take <Cholecalciferol soft capsules>

Do not take <Cholecalciferol soft capsules>

- If you are allergic to Cholecalciferol (vitamin D₃) or any of the other ingredients of this medicine (listed in section 6).
- if you have high levels of calcium in the blood (hypercalcaemia) or in the urine (hypercalciuria)
- if you suffer from kidney stones (nephrolithiasis) or calcium deposits in the kidneys (nephrocalcinosis).
- If you have high levels of vitamin D in the body (hypervitaminosis D).
- If you suffer from a kidney disease (renal failure) (see section “Warnings and precautions”).

Warnings and precautions

Talk to your doctor or pharmacist before taking <Cholecalciferol soft capsules>, especially:

- if you are an elderly person, if you are already taking medicines to treat heart diseases (cardiac glycosides or diuretics), if you have excess phosphate in your blood (hyperphosphataemia), or if you have an increased risk for stones (lithiasis). In these cases, your doctor will need to measure the levels of calcium in your blood or urine and to monitor your kidney function.

- If you have kidney damage or disease. In this case, your doctor will check your calcium and phosphate levels in the blood and urine.
- If you are already taking drugs containing vitamin D, food added with vitamin D, or milk enriched with vitamin D.
- If you suffer from a chronic inflammatory disease that may involve all organs called sarcoidosis.
- If you have an impairment of renal function, as vitamin D levels in the body may be altered.
- If you have a severe renal insufficiency: in this case other forms of vitamin D should be used.
- If you have an imbalance of your parathyroid hormone levels (pseudohypoparathyroidism).

Children and adolescents

<Cholecalciferol soft capsules> should not be used in children and adolescent under 18 years.

Other medicines and <Cholecalciferol soft capsules>

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, tell your doctor if you are taking the following medicines, as they can reduce or increase the effect of <Cholecalciferol soft capsules>:

- Medicines containing calcium
- Other medicines containing vitamin D.
- Medicines used for the treatment of epilepsy (anticonvulsants or barbiturates), such as phenytoin, phenobarbital, primidone, etc.
- Medicines to reduce fats in the blood such as colestipol, colestyramine, orlistat and laxatives (such as paraffin oil).
- Antiacids containing aluminium, medicines to treat too much acid in the stomach that can go up to the oesophagus.
- Antacidis medicines and preparations containing magnesium
- Glucocorticoids.
- Antifungal medicines.
- Thiazide diuretics (medicines to treat high blood pressure).
- Digitalis, a medicine to treat some heart disorders.
- Medicines used to treat tuberculosis, as rifampicin or isoniazide.
- Antifungal agents such as imidazole (such as ketoconazole), medicines used to stop the growth of fungal organisms.
- Medicines for the heart (cardiac glycosides); you should be monitored by your doctor. Your doctor may need to check your heart with a heart monitor ECG and measure the levels of calcium in your blood.

<Cholecalciferol soft capsules> with food and drink and alcohol

Tell your doctor if you take other product containing vitamin D, food added with vitamin D, or in case milk enriched with vitamin D is used, so that he/she can take into account the total dose of vitamin D taken and avoid excessive doses.

The intake of high quantities of alcohol for a long time (chronic alcoholism) decreases vitamin D deposits in the liver.

Pregnancy and breast-feeding

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.

<Cholecalciferol soft capsules> should not be used during pregnancy and breast-feeding. However, your doctor may decide that your clinical conditions necessarily require a treatment with

Cholecalciferol at lower dosages. Vitamin D₃ passes over into breast milk. This should be considered when giving additional vitamin D to the breast-fed child.

Driving and using machines

<Cholecalciferol soft capsules> has no or negligible influence on the ability to drive and use machines.

3 How to take <Cholecalciferol soft capsules>

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 the treatment shall be assessed by your doctor based on your health conditions.

Do not exceed the doses indicated by your doctor.

Take the dose orally.

<Cholecalciferol soft capsules> should be swallowed whole with water, preferably with the main meal of the day.

<Cholecalciferol soft capsules> 20 000 IU capsules

Prevention of Vitamin D deficiency:

The recommended dose is 1 capsule once a month.

Treatment of vitamin D deficiency:

The recommended dose is 1 capsule once a week for 4-5 weeks.

Your doctor may decide to lower the dose after the first month of treatment.

<Cholecalciferol soft capsules> 25 000 IU soft capsules

Prevention of Vitamin D deficiency:

The recommended dose is 1 capsule once a month.

Treatment of Vitamin D deficiency:

The recommended dose is 1 capsule once a week for 4 weeks.

Your doctor may decide to lower the dose after the first month of treatment.

Alternatively, it is possible to adhere to national recommendations regarding the dosages for the prevention and treatment of vitamin D deficiency.

If you take more < Cholecalciferol soft capsules> than you should

In case of accidental ingestion/intake of too much <Cholecalciferol soft capsules>, tell your doctor immediately or go to the nearest hospital.

In case of overdose, increased calcium levels in the blood and urine may occur, whose symptoms are the following: nausea, vomiting, thirst, increased quantity of urine output (polyuria), constipation, dehydration, diarrhoea, anorexia, headache, kidney stones, nephrocalcinosis, renal insufficiency, a persistent feeling of tiredness and lack of energy.

Chronic excessive overdoses may lead to deposits of calcium salts in the blood vessels and in organs.

If you forget to take <Cholecalciferol soft capsules>

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

If you stop taking <Cholecalciferol soft capsules>

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. The side effects reported with the use of vitamin D are the following:

Uncommon side-effects which may affect up to 1 in 100 people:
increased calcium levels in the blood (hypercalcaemia) and in urines (hypercalciuria).

Rare side-effects which may affect up to 1 in 1,000 people:
skin rash, itching, nettles.

Not Known (the frequency cannot be estimated from the available data):
Allergic reactions, diarrhoea, constipation, breaking wind (flatulence), tummy pain.

Hypercalcemia

Dependent on dose and duration of treatment of serious and persistent hypercalcemia with its acute (heart rhythm disturbances, dry mouth, metal taste, nausea, vomiting, kidney disease, headache, psychiatric symptoms, loss of consciousness) and chronic (increased urination, increased thirst, loss of appetite, weight loss, too much calcium in the kidneys, kidney calcification, calcification may in tissues outside the bone) episodes occur.

Reporting of side effects

If you get any side effects, talk to your doctor or, pharmacist.

This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in [Appendix V](#).*

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store< Cholecalciferol soft capsules>

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister and carton after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

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

Do not freeze.

This medicine does not require any special temperature storage conditions.

6. Contents of the pack and other information

What <Cholecalciferol soft capsule> contains

The active substance is cholecalciferol (vitamin D₃).

The other ingredients are:

- Fill: olive oil refined, butylhydroxytoluene (E321)
- Shell: glycerol 98% (E422), titanium dioxide (E171), gelatine succinate and allura Red (E129).

<Cholecalciferol soft capsules> 20 000 IU

Each soft capsule contains: cholecalciferol (vitamin D₃) 0.500 mg corresponding to 20 000 IU.

<Cholecalciferol soft capsules> 25 000 IU

Each soft capsule contains: cholecalciferol (vitamin D₃) 0.625 mg corresponding to 25 000 IU.

What <Cholecalciferol soft capsules> looks like and contents of the pack

<Cholecalciferol soft capsules> 20 000 IU

The pack contains 5 and 10 soft capsules in a PVC/PVDC and Aluminium thermo-sealed blister inserted in a cardboard box.

<Cholecalciferol soft capsules> 25 000 IU

The pack contains 2 and 4 soft capsules in a PVC/PVDC and Aluminium thermo-sealed blister inserted in a cardboard box.

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant

Vergunninghouder

Alfrapharma srl
Viale Manzoni, 59
00185 Rome
Italië

Fabrikant

DOPPEL FARMACEUTICI S.r.l.
Via Martiri delle Foibe, 1
29016 Cortemaggiore (PC)
Italië

In het register ingeschreven onder:

RVG 132429 Cholecalciferol Alfrapharma 20.000 IE zachte capsules

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Dit medicijn is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen:

Nederland: Cholecalciferol Alfrapharma 20.000 IE zachte capsules
Cholecalciferol Alfrapharma 25.000 IE zachte capsules
Italië: Colecalciferolo Alfrapharma

Deze bijsluiter is voor het laatst goedgekeurd in september 2026.