

PACKAGE LEAFLET: INFORMATION FOR THE USER

Colecalciferol 800 IU Capsules, Soft Colecalciferol

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

What Colecalciferol Capsules is and what it is used for

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1. What Colecalciferol capsules is and what it is used for

Colecalciferol capsules contains the active substance colecalciferol (vitamin D 3).

Vitamin D is found in the diet and is also produced in the skin after exposure to the sun. Vitamin D3 regulates the uptake and metabolism of calcium as well as the incorporation of calcium in bone tissue. Often vitamin D is given in combination with calcium.

Colecalciferol capsules may be prescribed by your doctor to treat or prevent vitamin D deficiency. Deficiency of vitamin D may occur when your diet or lifestyle does not provide you enough vitamin D or when your body requires more vitamin D (for instance when you are pregnant). Colecalciferol capsules may also be prescribed for certain bone conditions, such as thinning of the bone (osteoporosis) when it will be given to you with other medicines.

Colecalciferol capsules is used in adults, the elderly and adolescents.

2. What you need to know before you take Colecalciferol capsules

Do not take Colecalciferol capsules:

- if you are allergic to vitamin D or any of the other ingredients of this medicine (listed in section 6);
- if you have high levels of vitamin D in your blood (hypervitaminosis D);
- if you have kidney stones or calcium deposits in your kidneys;
- if you have high levels of calcium in your blood (hypercalcaemia) or urine (hypercalciuria);
- if you have severe kidney problems (severe renal impairment).

If any of the above applies to you, tell your doctor or pharmacist before taking Colecalciferol capsules.

Warnings and precautions

Talk to your doctor or pharmacist before taking Colecalciferol capsules. In particular, tell your doctor if:

- you have high tendency to kidney stone formation;
- you are being treated for heart disease;
- you have cancer or any other condition that may have affected your bones;
- you have parathyroid hormone imbalance (pseudohypoparathyroidism).

If you have any of the following conditions, your doctor will monitor the levels of calcium

or phosphate in your blood, or the level of calcium in your urine:

- you are on long term treatment with this medicine or are already taking additional doses of calcium or vitamin D;
- you have kidney problems;
- you suffer from sarcoidosis (an immune system disorder which may affect your liver, lungs, skin or lymph nodes).

Children

Colecalciferol capsules is not indicated for use in children under 12 years.

Other medicines and Colecalciferol capsules

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

This is especially important if you are taking:

- calcium containing products in high doses, as these increase the risk of high blood calcium levels.
- heart medicines (cardiac glycosides such as digoxin). Your doctor may monitor your heart with an electrocardiogram (ECG) and measure the levels of calcium in your blood.
- thiazide diuretics (used to treat high blood pressure), as these reduce the urinary excretion of calcium and can increase the risk of high blood calcium levels.
- anticonvulsants medicines used to treat epilepsy (such as phenytoin) or medicines to make you sleep (hydantoin or barbiturates such as phenobarbitone), as these can decrease the effects of vitamin D.
- glucocorticoids (steroid hormones such as hydrocortisone or prednisolone), as these can decrease the effects of vitamin D.
- magnesium containing products (e.g. antacids), as these should not be used during treatment with vitamin D because of the risk of high magnesium levels.
- calcitonin, etidronate, gallium nitrate, pamidronate or plicamycin, as these decrease blood calcium levels.
- phosphorus containing products in large doses, as these in large doses increase the risk of high phosphate blood levels.
- laxatives (such as paraffin oil), or a cholesterol lowering medicine called colestyramine, as these may reduce the absorption of vitamin D.
- actinomycin (a medicine used to treat some forms of cancer) and imidazole antifungals (medicines such as clotrimazole and ketoconazole used to treat fungal diseases), as these may interfere with the metabolism of vitamin D.

Colecalciferol capsules with food and drink

You can take Colecalciferol capsules with or without food.

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.

Colecalciferol capsules can be used during pregnancy, but only if you have been diagnosed with vitamin D deficiency and following the advice of your doctor.

Driving and using machines

Colecalciferol capsules should not affect your ability to drive or operate machinery.

Colecalciferol contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per 800 IU, that is to say essentially 'sodium-free'.

3. How to take Colecalciferol 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 recommended doses are:

Severe vitamin D deficiency (for adults and the elderly)

Your doctor will usually prescribe you a dose of 1-4 capsules daily for up to 12 weeks. The amount will depend on how low your vitamin D levels are and how you respond to treatment. Your doctor will then tell you to take 1-2 capsules daily to maintain your vitamin D levels.

Moderate vitamin D deficiency (for adults and the elderly) or prevention of vitamin D deficiency
Your doctor will usually prescribe 1-2 capsules daily.

Osteoporosis (you will also be taking other medicines for this)

Your doctor will usually prescribe 1 capsule daily. You should check with your doctor or pharmacist if you are unsure.

Use in children and adolescents

Vitamin D deficiency in adolescents over 12 years
Your doctor will usually prescribe you 1 capsule daily.

Children below 12 years

Colecalciferol capsules is not suitable for children under 12 years.

Method of administration

Swallow the capsules whole with water. Do not chew the capsules.

If you take more Colecalciferol capsules than you should

If you accidentally take one capsule too many, nothing is likely to happen. If you accidentally take several capsules too many, tell your doctor or get other medical advice immediately. If possible, take the capsules, the box and this leaflet with you to show the doctor. If you take too many capsules, you may develop the following symptoms: feeling or being sick, having to pass urine more than usual, lack of appetite, tiredness, thirst, constipation, stomach pains, muscle weakness, confusion, bone pain, kidney problems, dizziness and in severe cases irregular heartbeats, coma or even death.

If you forget to take Colecalciferol capsules

If you forget to take your capsules, take them as soon as you can. Then take the next dose at the correct time, in accordance with the instructions given to you by your doctor.

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, Colecalciferol capsules can cause side effects, although not everybody gets them. Stop taking Colecalciferol capsules and seek immediate medical help if you experience symptoms of serious allergic reactions, such as:

- swollen face, lips, tongue or throat
- difficulty to swallow
- hives and difficulty breathing.

Side effects with Colecalciferol capsules may include:

Uncommon (may affect up to 1 in 100 people)

- too much calcium in your blood (hypercalcaemia). Symptoms include feeling or being sick, lack of appetite, constipation, stomach ache, bone pain, feeling very thirsty, a need to pass more water than usual, muscle weakness, drowsiness or confusion.
- too much calcium in your urine (hypercalciuria).

Rare (may affect up to 1 in 1000 people)

- skin rash
- itching
- hives (raised itchy rash)

Tell your doctor or pharmacist if any of the side effects become serious or if you notice any side effects not listed.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Colecalciferol capsules

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

This medicine does not require any special temperature storage conditions. Keep the blister in the outer carton in order to protect from light.

Do not use Colecalciferol capsules after the expiry date which is stated on the carton as "EXP". The expiry date refers to the last day of that month.

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

6. Contents of the pack and other information

What Colecalciferol capsules contains

The active substance is Colecalciferol. Each capsule contains 800 IU Colecalciferol (equivalent to 20 micrograms Vitamin D3).

The other ingredients are:

Capsule content:

maize oil, refined.

Capsule shell:

gelatin, glycerol (E 422),

Brilliant Blue FCF (E 133)

What Colecalciferol capsules looks like and contents of the pack

Colecalciferol 800 IU Capsule is a translucent blue capsule and has no markings.

It is available in blister packs containing 28, 30, 56, 60 or 90 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder:

Strides Pharma (Cyprus) Limited
Themistokli Dervi, 3
Julia House
1066, Nicosia
Cyprus

Manufacturer:

Fairmed Healthcare GmbH,
Maria- Goeppert-Strasse 3,
Luebeck, Schleswig- Holstein,
23562, Germany

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

United Kingdom (Northern Ireland)	STRIVIT-D3 800 IU Capsules, Soft Colecalciferol 800 IU capsules, soft
Denmark	Colecalciferol 800 IU capsules, soft
Netherlands	Colecalciferol Strides 800 IE capsule, zacht
Sweden	Kolekalciferol Strides 800 IE kapsel, mjuk
Norway	Kolekalsiferol Strides
Ireland	Colecalciferol Soft cap 800IU

This leaflet was last revised in 09/2023.