

Package leaflet: Information for the user

Vitamin D₃ 800 IU Capsules, soft

Vitamin D₃ 1,000 IU Capsules, soft

Vitamin D₃ 10,000 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

1. What Vitamin D₃ Capsules are and what they are used for
2. What you need to know before you take Vitamin D₃ Capsules
3. How to take Vitamin D₃ Capsules
4. Possible side effects
5. How to store Vitamin D₃ Capsules
6. Contents of the pack and other information

1. WHAT VITAMIN D₃ CAPSULES ARE AND WHAT THEY ARE USED FOR

The active substance of Vitamin D₃ Capsules is vitamin D₃. Vitamin D helps the body to absorb calcium and enhances bone formation.

This medicine is recommended in the following cases:

- For certain bone conditions, such as thinning of the bone (osteoporosis), when it will be given to you with other medicines.
- To prevent or treat vitamin D deficiency. Vitamin D deficiency may occur when your diet or lifestyle does not provide you enough vitamin D or when your body requires more vitamin D.

Vitamin D₃ Capsules are used in adults, the elderly and adolescents.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE VITAMIN D₃ CAPSULES

Do not take Vitamin D₃ 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 calcium in your blood (hypercalcaemia) or urine (hypercalciuria)
- if you have severe kidney problems (severe renal impairment)
- if you have high levels of vitamin D in your blood (hypervitaminosis D)
- if you have kidney stones or calcium deposits in your kidneys.

Warnings and precautions

Talk to your doctor or pharmacist before taking Vitamin D₃ Capsules if:

- You have high tendency to kidney stone formation.
- 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:

- if you are on long term treatment with this medicine
- if you have kidney problems
- if you suffer from 'sarcoidosis'; an immune system disorder which may affect your liver, lungs, skin or lymph nodes.

Children

Vitamin D₃ Capsules are not indicated for use in children under 12 years.

Other medicines and Vitamin D₃ 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:

- diuretics (water tablets). As your doctor will need to monitor your blood calcium levels regularly
- corticosteroids ('steroids' e.g. prednisolone, dexamethasone). As your dose of vitamin D may need to be increased
- colestyramine (a cholesterol lowering medicine) or laxatives (e.g. paraffin oil). As they reduce vitamin D absorption
- heart medicines (cardiac glycosides). As you should be monitored by a physician and possibly an ECG and your calcium levels monitored
- anticonvulsants (for the treatment of epilepsy), sleeping medicines (e.g. hydantoin barbiturates) or primidone. As these reduce the effect of vitamin D
- calcitonin, etidronate, gallium nitrate, pamidronate or plicamycin. As these decrease blood calcium levels
- calcium containing products in high doses. As these increase the risk of high blood calcium levels
- 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
- phosphorus containing products in large doses. As these in large doses increase the risk of high phosphate blood levels.

Vitamin D₃ Capsules with food and drink

You can take Vitamin D₃ 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. These formulations 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

There is limited information on the possible effects of this medicine on your ability to drive. However, it is not expected that it would affect your ability to drive or operate machinery.

Vitamin D₃ Capsules contain:

Sorbitol: If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Sunset yellow (10,000 IU only): Vitamin D₃ 10,000 Capsules contain sunset yellow which may cause an allergic reaction.

Continued overleaf...

3. HOW TO TAKE VITAMIN D₃ 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.

Adults

800 IU and 1,000 IU Vitamin D₃ Capsules:

Your doctor will usually prescribe 1 capsule daily. In severe vitamin D deficiency for the adult and the elderly, the amount will depend on your vitamin D levels and on the response given to the treatment.

10,000 IU Vitamin D₃ Capsules:

Your doctor will usually prescribe 1 capsule every week. In severe vitamin D deficiency for the adult and the elderly, the amount will depend on your vitamin D levels and on the response given to the treatment.

Adolescents

800 IU Vitamin D₃ Capsules:

Your doctor will usually prescribe 1 capsule daily. The amount will depend on your vitamin D levels and on the response given to the treatment.

Use in children

Vitamin D₃ Capsules are not suitable for children under 12 years.

Method of administration

You should swallow the capsules whole with water, do not chew the capsules.

If you take more Vitamin D₃ Capsules than you should

You may develop the following symptoms: loss of appetite, thirst, nausea, vomiting, constipation, abdominal pain, muscle weakness, tiredness, confusion, having to pass urine more than usual, bone pain, kidney problems and in severe cases, irregular heartbeat, coma or even death.

If you take too many capsules, contact your doctor immediately or go to the emergency department of the nearest hospital. Take the packet and any remaining capsules with you.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

If you forget to take Vitamin D₃ Capsules

If you forgot to take a dose of Vitamin D₃ Capsules, take the forgotten dose as soon as possible. Then take the next dose at the correct time. 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.

After that, take the next capsule in accordance with the instructions given to you by your doctor. 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.

Stop taking Vitamin D₃ Capsules and seek immediate medical help if you experience symptoms of serious allergic reactions, such as:

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

Side effects with Vitamin D₃ Capsules may include:

Uncommon (may affect up to 1 in 100 people):

- too much calcium in your blood (hypercalcaemia). Symptoms include nausea, vomiting, lack of appetite, constipation, stomach ache, bone pain, extreme thirst, a need to pass more water than usual, muscle weakness, drowsiness and confusion
- too much calcium in your urine (hypercalciuria).

Rare (may affect up to 1 in 1,000 people):

- skin rash (pruritus, urticaria)
- itching.

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.

UK: Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Ireland: 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 VITAMIN D₃ CAPSULES

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

Store below 30°C.

HDPE Containers and Amber Glass Bottles: Once opened use within 105 days.

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

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Vitamin D₃ Capsules contain

– The active substance is colecalciferol:

Each 800 IU capsule contains 800 IU of colecalciferol, equivalent to 20 micrograms Vitamin D₃.

Each 1,000 IU capsule contains 1,000 IU of colecalciferol, equivalent to 25 micrograms Vitamin D₃.

Each 10,000 IU capsule contains 10,000 IU of colecalciferol, equivalent to 250 micrograms Vitamin D₃.

– The other ingredients are:

Capsule: medium chain triglycerides and vitamin E acetate (α -tocopheryl acetate).

Capsule shell 800 IU: Gelatin, glycerol, sorbitol liquid partially dehydrated, brilliant blue and purified water.

Capsule shell 1,000 IU: Gelatin, glycerol, sorbitol liquid partially dehydrated, brilliant blue, quinoline yellow and purified water.

Capsule shell 10,000 IU: Gelatin, glycerol, sorbitol liquid partially dehydrated, sunset yellow and purified water.

What Vitamin D₃ Capsules looks like and contents of the pack

– Vitamin D₃ 800 IU Capsules are blue coloured, clear transparent round shaped gelatin capsules with a clear, colourless liquid fill.

– Vitamin D₃ 1,000 IU Capsules are green coloured, clear transparent round shaped gelatin capsules with a clear, colourless liquid fill.

– Vitamin D₃ 10,000 IU Capsules are orange coloured, clear transparent round shaped gelatin capsules with a clear, colourless liquid fill.

Vitamin D₃ Capsules are available in glass amber bottles, HDPE bottles and blister strips containing 20, 30, 50, 60 or 90 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Alissa Healthcare Research Limited, Unit 5 Fulcrum 1, Solent Way, Whiteley, Fareham, Hampshire, United Kingdom, PO15 7FE

Manufacturer:

Geryon Pharma Limited, 18 Owen Drive, Liverpool, L24 1YL, United Kingdom

This medicinal product is authorised in the Member States of the EEA under the following names:

Ireland & United Kingdom: Vitamin D₃ 800 IU Capsules, soft

Ireland & United Kingdom: Vitamin D₃ 1,000 IU Capsules, soft

Ireland & United Kingdom: Vitamin D₃ 10,000 IU Capsules, soft

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