



Package Leaflet: Information for the user STRIVIT-D3 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

1. What STRIVIT-D3 is and what it is used for
2. What you need to know before take STRIVIT-D3
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1. What STRIVIT-D3 is and what it is used for

STRIVIT-D3 contains the active substance Colecalciferol.

Vitamin D is found in the diet and is also produced in the skin after exposure to the sun. Often vitamin D is given in combination with calcium. STRIVIT-D3 is recommended for use when you have a normal intake of dietary calcium.

STRIVIT-D3 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). STRIVIT-D3 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.

2. What you need to know before you take STRIVIT-D3

Do not take STRIVIT-D3

- if you are allergic (hypersensitive) to vitamin D or any of the other ingredients in the capsules (these are listed in section 6, Further information)
- if you have high levels of vitamin D in your blood (hypervitaminosis D)
- if you have high blood levels of calcium (hypercalcaemia) or high urine levels of calcium (hypercalciuria)
- if you have kidney stones or serious kidney problems.

If any of the above applies to you, tell your doctor or pharmacist before taking STRIVIT-D3.

Warnings and precautions

Talk to your doctor before taking STRIVIT-D3

- if you have kidney damage or disease. Your doctor may want to measure the levels of calcium in your blood or urine.
- if you are being treated for heart disease
- you have sarcoidosis (an immune system disorder which may affect your liver, lungs, skin or lymph nodes)
- if you are already taking additional doses of calcium or vitamin D. Whilst you are taking STRIVIT-D3 your doctor will monitor your blood levels of calcium to make sure they are not too high.

Other medicines and STRIVIT-D3

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

In particular the following medicines may interact with STRIVIT-D3:

- **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) reduce the urinary excretion of calcium and can increase risk of hypercalcaemia.
- **Medicines used to treat epilepsy** (such as phenytoin) or medicines to make you sleep (barbiturates such as phenobarbitone) can decrease the effects of vitamin D.
- **Glucocorticoids** (steroid hormones such as hydrocortisone or prednisolone) can decrease the effects of vitamin D.
- **Laxatives** (such as paraffin oil), or a cholesterol lowering drug called colestyramine, 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) may interfere with the metabolism of vitamin D.

STRIVIT-D3 with food and drink

You can take STRIVIT-D3 with or without food and drink.

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.

Driving and using machines

STRIVIT-D3 should not affect your ability to drive or operate machinery.

3. How to take STRIVIT-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 recommended dose is:

In 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.

In moderate vitamin D deficiency (for adults and the elderly) or to prevent vitamin D deficiency

Your doctor will usually prescribe 1-2 capsules daily.

In vitamin D deficiency in children over 12 years

Your doctor will usually prescribe you 1 capsule daily.

In 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.

The capsules should be swallowed whole (not chewed) with water.

STRIVIT-D3 is not suitable for children under 12 years.

If you take more STRIVIT-D3 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 feel or be sick, become constipated or have stomach pains, weak muscles, tiredness, lack of appetite, kidney problems and in severe cases irregular heartbeats.

If you forget to take STRIVIT-D3

If you forget to take your capsules, take them as soon as you can. 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 product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, STRIVIT-D3 can cause side effects, although not everybody gets them.

Side effects with STRIVIT-D3 may include:

Uncommon side effects (affecting less than 1 in 100 people)

- Too much calcium in your blood (hypercalcaemia). You may feel or be sick, lose your appetite, have constipation, stomach ache, feel very thirsty, have muscle weakness, drowsiness or confusion.
- Too much calcium in your urine (hypercalciuria).

Rare side effects (affecting less than 1 in 1000 people)

- Skin rash
- Itching
- Hives

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store STRIVIT-D3

Keep out of the reach and sight 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 STRIVIT-D3 after the expiry date which is stated on the carton as "EXP". The expiry date refers to the last day of that month. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What STRIVIT-D3 contains

The active ingredient (which makes the medicine work) 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 Supra containing Brilliant blue for coloring of food (E133), sodium chloride and sodium sulphate
Purified Water

What STRIVIT-D3 looks like and contents of the pack

STRIVIT-D3 800 IU Capsule is a translucent blue capsule (size 2) 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 Arcolab International Ltd.
Unit 4, Metro Centre, Tolpits Lane,
Watford, Hertfordshire WD18 9SS,
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Manufacturer:
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