

**Package Leaflet: Information for the user**  
**Colecalciferol 3,200 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 Colecalciferol capsules is and what it is used for
2. What you need to know before you take Colecalciferol capsules
3. How to take Colecalciferol capsules
4. Possible side effects
5. How to store Colecalciferol capsules
6. Contents of the pack and other information

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

Colecalciferol capsules contains the active substance Colecalciferol (vitamin D3). 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 is recommended for use when you have a normal intake of dietary 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).

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

**Do not take Colecalciferol capsules:**

- if you are allergic to colecalciferol 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 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, do not take Colecalciferol capsules.

**Warnings and precautions**

Talk to your doctor or pharmacist before taking Colecalciferol capsules:

- if you have kidney damage or disease and long term treatment with this medicine. 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 Colecalciferol capsules your doctor will monitor your blood levels of calcium to make sure they are not too high.

**Children and adolescents**

Colecalciferol capsules is not suitable for 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.

In particular the following medicines may interact with Colecalciferol capsules:

- **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 (colestyramine, colestipol), orlistat 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.

**Colecalciferol capsules with food and drink**

You can take Colecalciferol capsules 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. If you require extra vitamin D, do not take it without the supervision of your doctor. Too much vitamin D may harm your baby.



Dimension - 140 x 240 mm

Front Side

Non Printing Colour

**ARTWORK DETAIL LABEL**

<b>Product</b>	Colecalciferol 3,200 IU capsules, soft Colecalciferol			
Buyer/Country	SPUK	Component	Pack Insert	
<b>Dimension</b>	140 x 240 mm	Pack	----	
<b>New Item Code</b>	1048276	Old Item Code	1047517	
Colour Shades	■ BLACK	No. of Colours	1	
Change Control No.	PC-TSG/2022/050 - Record Number: 333166		Artwork Version	3.0
Design/Style	Front & Back side printing, To be supplied in a unfolded size.			
Substrate	60 GSM Paper.			
Special Instructions	PRINTING CLARITY TO BE CLEAR AND SHARP.			
Autocartonator Requirements	Pack insert supply should be as per auto-cartonator. Refer auto-cartonator drawing for instructions.			
<b>Caution to the printer:</b> Before processing, please ensure that the ARTWORK received for printing is exactly in line with APPROVED ARTWORK provided to you. In case of any FONTS/DESIGN are Mis-matching with the APPROVED ARTWORK, please inform PDC for further action. <b>DO NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM PDC.</b>				

**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 3,200 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 capsules should be swallowed whole with water and can be taken with or without food. The recommended dose is:

**In severe vitamin D deficiency (for adults and the elderly)**  
 Your doctor will usually prescribe you a dose of 1 capsule daily for up to 12 weeks. The amount will depend on how low your vitamin D levels are and how you respond to treatment.

**Use in children**  
 Colecalciferol capsules is not suitable for children under 12 years.

**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 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 Colecalciferol capsules**  
 If you forget to take your capsules, take them as soon as you can. After that, take the next capsule in accordance with the instructions given to you by your doctor.

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, this medicine can cause side effects, although not everybody gets them. Stop taking Colecalciferol 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 may include

**Uncommon** (may affect up to 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** (may affect up to 1 in 1,000 people)

- skin rash;
- itching;
- hives.

**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](http://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 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 this medicine after the expiry date which is stated on the 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 to protect the environment.

**6. Contents of the pack and other information**

**What Colecalciferol capsules contains**

- The active ingredient is colecalciferol. Each capsule contains 3,200 IU colecalciferol (equivalent to 80 micrograms Vitamin D3).
- The other ingredients are:



**Capsule Content:** maize oil, refined

**Capsule Shell:** gelatin, glycerol (E 422), chlorophyllin copper complex sodium (E141)

**What Colecalciferol looks like and contents of the pack**  
 Colecalciferol 3,200 IU Capsule is a translucent green to greenish yellow coloured and has no markings. It is available in blister packs containing 7, 10, 14, 20, 28, 30, 56, 60, 84 or 90 capsules. Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**  
 Strides Pharma UK Ltd.  
 Unit 4, The Metro Centre Dwight Road,  
 Watford, WD18 9SS  
 United Kingdom

**This leaflet was last revised in 12/2022.**

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Back Side

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