

10311



**Package Leaflet: Information for the user**  
**Colecalciferol 20,000 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 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 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 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.

**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.

Due to their high strength, Colecalciferol 20,000 IU capsules are not recommended during pregnancy and breast-feeding.

**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 20,000 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.



10311

Dimension - 140 x 300 mm

Front Side

**ARTWORK DETAIL LABEL**

Non Printing Colour

<b>Product</b>	Colecalciferol 20,000 IU capsules, soft Colecalciferol		
<b>Buyer/Country</b>	SPUK	<b>Component</b>	Pack Insert
<b>Dimension</b>	140 x 300 mm	<b>Pack</b>	----
<b>New Item Code</b>	1048277	<b>Old Item Code</b>	1047518
<b>Colour Shades</b>	■ BLACK	<b>No. of Colours</b>	1
<b>Change Control No.</b>	PC-TSG/2022/050 - Record Number: 333166		<b>Artwork Version</b> 3.0
<b>Design/Style</b>	Front & Back side printing, To be supplied in a unfolded size.		
<b>Substrate</b>	60 GSM Paper.		
<b>Special Instructions</b>	PRINTING CLARITY TO BE CLEAR AND SHARP.		
<b>Autocartonator Requirements</b>	<b>Pack insert supply should be as per auto-cartonator. Refer auto-cartonator drawing for instructions.</b>		
<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>			

RD/PD/003/F-08/R0

The capsules should be swallowed whole with water and can be taken with or without food. The recommended dose and dosage schedules are:

**In treatment of vitamin D deficiency (for adults and the elderly)**

The recommended dose is 800 IU per day or equivalent weekly or monthly dose [20,000 IU (1 capsule) per month]. The dose should not exceed 4,000 IU per day or equivalent weekly or monthly dose.

**In prevention of vitamin D deficiency (for adults and the elderly)**

Recommended dose range is 600 IU- 800 IU per day or equivalent weekly or monthly dose [20,000 IU (1 capsule) per month].

**Use in children and adolescents (12 - 18 years)**

*For children*

Colecalciferol 20,000 IU capsules should not be given to children under 12 years of age due to the risk of choking. Instead, it is advisable to use drops or dissolvable tablets.

*For adolescents*

The daily dose should not exceed 4,000 IU per day or equivalent weekly [20,000 IU (1 capsule) per week] or monthly dose.

The dose should be adjusted depending on the severity of the disease and the patient's response to treatment. Should only be given under medical supervision.

**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 Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

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 20,000 IU colecalciferol (equivalent to 500 micrograms Vitamin D3).
- The other ingredients are:

**Capsule Content:** maize oil, refined

**Capsule Shell:** gelatin, glycerol (E 422)

**What Colecalciferol capsules looks like and contents of the pack**

Colecalciferol 20,000 IU Capsule is a clear colourless to pale yellow coloured translucent oval shaped soft gelatin capsules containing clear colourless to pale yellow coloured oily liquid.

It is available in blister packs, Containing 7, 10, 14, 15, 20, 28 or 30 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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