

**Package leaflet: Information for the Patient**  
**Colecalciferol 1 000 IU Capsules**

**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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

**What is in this leaflet**

1. What Colecalciferol Capsules are and what they are 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 are and what they are used for**

Colecalciferol Capsules contain the active ingredient colecalciferol. Colecalciferol is a form of vitamin D used in the prevention and treatment of vitamin D deficiency conditions. It 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 1 000 IU is the equivalent of 25 micrograms vitamin D<sub>3</sub>, which is involved in bone formation.

The active ingredient colecalciferol is identical to the Colecalciferol that is found in the human body. It is found in the diet and is also produced in the skin after exposure to the sun.

Deficiency of vitamin D may occur when your diet or lifestyle does not provide you with enough vitamin D or when your body requires more vitamin D (for instance when you are pregnant).

**If you are planning to get pregnant or you are pregnant and you require extra vitamin D do not take it without medical supervision.**

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

**Do not take Colecalciferol Capsules**

- If you are **allergic** (hypersensitive) to Colecalciferol or any of the other ingredients in the capsules (these are listed in section 6. Contents of the pack and other information)
- if you have **high levels of calcium** in your blood (hypercalcaemia) or urine (hypercalciuria)
- if you are suffering from **kidney failure**, have **kidney stones (renal calculi)** or have a **tendency to form kidney stones**
- if you have **high levels of vitamin D** in your blood (hypervitaminosis D).

## Warnings and precautions

Talk to your doctor or pharmacist before taking Colecalciferol Capsules:

- if you suffer from **heart disease** or narrowing of the arteries
- if you suffer from **sarcoidosis** (a multisystem chronic inflammatory condition which can affect your lungs, heart and kidneys), then there is a risk of increased conversion of vitamin D into its active form
- if you are taking medicines **containing vitamin D**, or eating foods or drinking milk enriched with vitamin D.

Your doctor may want you to have regular blood tests to check the amount of calcium in your blood.

## Children and adolescents

Colecalciferol Capsules should only be given to children and adolescents aged 12 and over.

## Other medicines and Colecalciferol Capsules

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes any medicines which you have bought without a prescription.

You must **tell your doctor or pharmacist** if you are taking any of the following medicines:

- medicines for **epilepsy** such as barbiturates or other anti-convulsants (e.g. carbamazepine, phenobarbital, phenytoin, primidone)
- other **vitamin D containing medicines** including **multi-vitamins**
- medicines to control the **rate of your heart beat** (e.g. digoxin, digitoxin)
- **diuretics** (water tablets) such as bendroflumethiazide
- **calcium supplements**
- medicines to treat **tuberculosis** e.g rifampicin, isoniazid
- medicines leading to **fat malabsorption** e.g orlistat, cholestyramine, liquid paraffin
- medicines to treat **fungal infections** i.e. ketoconazole, itraconazole
- **actinomycin** (a medicine used to treat some forms of cancer) as it may interfere with the metabolism of vitamin D
- **glucocorticosteroids** (steroid hormones such as hydrocortisone or prednisolone).

## 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 medical supervision because **too much** vitamin D may harm your baby.

## Driving and using machines

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

## Colecalciferol Capsules contains azorubine, carmoisine

Azorubine, carmoisine may cause allergic reaction.

### 3. **How to take Colecalciferol Capsules**

Always take this medicine exactly as your doctor or pharmacist has told you and as written on the label. Check with your doctor or pharmacist if you are not sure.

#### **Recommended Doses**

##### Adults

- **Treatment of vitamin D deficiency:** 1-4 capsules (1 000 - 4 000 IU) daily for 10 weeks, followed by maintenance therapy of 1-2 capsules (1 000 - 2 000 IU) daily, as directed by your doctor.

- **Prevention of vitamin D deficiency:** 1-2 capsules (1 000 - 2 000 IU) daily, as directed by your doctor. Higher doses may be required in certain populations.

- **In osteoporosis (you will also be taking other medicines for this):** 1 capsule (1 000 IU) daily, as directed by your doctor.

##### Children and adolescents (12- 18 years)

-**Treatment or prevention of vitamin D deficiency:** 1 capsule (1 000 IU) daily, as directed by your doctor.

If you have problems absorbing vitamin D or have other conditions such as liver disease the dose may be different and will depend on your medical condition.

**It is important not to exceed the prescribed dose.**

#### **Colecalciferol Capsules with food and drink**

The capsules should be swallowed whole with a glass of water, preferably with the main meal of the day.

#### **Use in children and adolescents**

Colecalciferol Capsules should only be given to children and adolescents aged 12 and over.

#### **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 forget to take Colecalciferol Capsules**

If you forget to take your capsules, take them as soon as possible. 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.

Side effects with Colecalciferol Capsules 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
- raised itchy rash (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 to the relevant medicine authority (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

#### **United Kingdom:**

Yellow Card Scheme

Website:

[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

### **5. How to store Colecalciferol Capsules**

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

Store below 25°C.

Store in the original package to protect from light and moisture.

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 Colecalciferol Capsules contain**

The active substance is Colecalciferol. Each capsule contains: 1 000 IU colecalciferol (equivalent to 25 micrograms vitamin D<sub>3</sub>).

The other ingredients are medium-chain triglycerides, butylated hydroxytoluene (BHT), colloidal anhydrous silica, purified water, polysorbate 80, red iron oxide, yellow iron oxide, titanium dioxide, azorubine carmoisine and gelatin.

#### **What Colecalciferol Capsules look like and contents of the pack**

Colecalciferol Capsules is an unprinted, hard gelatin red capsule containing clear, slightly yellow oily liquid.

Capsule length: 21.7 mm.

It is available in blister packs containing 10, 14, 20, 28, 30, 56, 60, 84, 100 capsules.  
Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

**Marketing Authorisation Holder**

Colonis Pharma Limited,  
25 Bedford Square  
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**Manufacturer**

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