

# Colextra-D3

Package leaflet: Information for the user

**Colextra-D3 25,000 IU Tablets**  
**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 Colextra-D3 Tablets are and what they are used for
2. What you need to know before you take Colextra-D3 Tablets
3. How to take Colextra-D3 Tablets
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## 1. What Colextra-D3 Tablets are and what they are used for

Colextra-D3 Tablets contain the active substance Vitamin D3, also known as 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. Colextra-D3 tablets are recommended for use when you have a normal intake of dietary calcium.

Colextra-D3 Tablets 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). Colextra-D3 tablets 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 Colextra-D3 Tablets

### Do not take Colextra-D3 Tablets:

- If you are allergic (hypersensitive) to vitamin D or any of the other ingredients in the tablets (listed in Section 6)
- If you have high levels of vitamin D in your blood (hypervitaminosis D)
- If you have high levels of calcium (hypercalcaemia) or high urine levels of calcium (hypercalciuria)
- If you have kidney stones or serious kidney problems

### Warnings and precautions

#### Check with your doctor before taking Colextra-D3 Tablets:

- 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
- If 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 Vitamin D3 your doctor will monitor your blood levels of calcium to make sure they are not too high

### Children and adolescents

Do not give this medicine to children and adolescents under 12 years of age.

### Other medicines and Colextra-D3 Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

In particular, the following medicines may interact with Colextra-D3 Tablets:

- 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 the risk of hypercalcaemia
- Medicines to treat epilepsy (such as phenytoin) or medicines to make you sleep (barbiturates such as phenobarbitone) as these medicines can decrease the effect of vitamin D
- Glucocorticoids (steroid hormones such as hydrocortisone or prednisolone). These can decrease the effect of vitamin D

synergy biologics 

- 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) as they may interfere with the metabolism of vitamin D.

### 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. Colextra-D3 Tablets should be used during pregnancy and breast-feeding only if recommended by your doctor.

### Driving and using machines

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

### Colextra-D3 Tablets contains sucrose

Colextra-D3 25,000 IU Tablets contain 43.75 mg of sucrose in each tablet.

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

## 3. How to take Colextra-D3 Tablets

Always take Colextra-D3 Tablets exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

### Recommended Dose in Adults

Prevention of vitamin D deficiency	<b>Colextra-D3 25,000 IU Tablets</b> 1 tablet every 4-6 weeks as directed by your doctor
In osteoporosis (you will also be taking other medicines for this)	<b>Colextra-D3 25,000 IU Tablets</b> 1 tablet every 4-6 weeks as directed by your doctor
Treatment of vitamin D deficiency:	<b>Colextra-D3 25,000 IU Tablets</b> 1 tablet every 4 weeks as directed by your doctor

The dose may be adjusted depending on the severity of the disease and your response to the treatment.

#### **Recommended Dose in Adolescents 12-18 years of age**

Your doctor will decide the dose. The dose will be dependent on the severity of the disease and your response to the treatment.

#### **Use in Children under 12 years of Age**

Colextra-D3 Tablets should not be given to children under 12 years of age.

If you have problems absorbing Colextra-D3 or have other conditions such as liver disease, the dose of Colextra-D3 may be different. This will be directed by your doctor.

During long term treatment, the calcium levels in blood and urine and the function of the kidney will be monitored regularly by your doctor to ensure you are taking correct dose.

#### **Method of administration**

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

#### **If you take more Colextra-D3 Tablets than you should**

If you accidentally take one tablet too many, nothing is likely to happen. If you accidentally take several tablets too many tell your doctor or get other medical advice immediately. If possible, take the tablets, the box and this leaflet with you to show the doctor. If you take too many tablets 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 Colextra-D3 Tablets**

If you forget to take your tablets, 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 tablets as scheduled

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.

Side effects with Colextra-D3 Tablets may include:

**Uncommon side effects** (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 side effects** (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) or by searching 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 Colextra-D3 Tablets**

Keep this medicine out of the sight and reach of children. Store below 25°C. Keep the blister in the outer carton in order to protect from light.

For Colextra-D3 25,000 IU tablets packaged in a container, store in the original package in order to protect from light.

Do not use Colextra-D3 Tablets after the expiry date which is stated on the carton and container/blister as "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 required. These measures will help to protect the environment.

# Colextra-D3

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

##### **What Colextra-D3 Tablets contain**

The active substance is Colecalciferol (Vitamin D3).

Colextra-D3 25,000 IU Tablets: Each tablet contains 25,000 IU Colecalciferol (equivalent to 625 micrograms vitamin D3)

The other ingredients are:  
modified food starch  
medium chain triglycerides  
dl-alpha-tocopherol  
sodium ascorbate  
sucrose  
silicon dioxide  
microcrystalline cellulose  
hydroxypropyl cellulose  
low-substituted silica  
colloidal anhydrous

##### **What Colextra-D3 Tablets look like and contents of the pack**

Colextra-D3 25,000 IU Tablets: Colextra-D3 25,000 IU Tablet is a white, or almost white, oval, biconvex tablet, plain on both sides with dimensions 17 mm x 8 mm.

It is available in blister packs containing 4, 6 and 12 tablets. Not all pack sizes may be marketed.

##### **Manufacturer**

Meditop Pharmaceutical Ltd.  
Ady Endre street 1  
2097 Pilisborosjenő Hungary

##### **Marketing Authorisation Holder**

Synergy Biologics Limited  
Unit 1, The Stamp Factory  
Wednesbury Road  
Walsall, West Midlands  
WS1 3QY  
United Kingdom

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