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Package leaflet: Information for the user

Colextra-D3 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 Colextra-D3 capsules are and what they are used for
2. What you need to know before you take Colextra-D3 capsules
3. How to take Colextra-D3 capsules
4. Possible side effects
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1. What Colextra-D3 capsules are and what they are used for

Colextra-D3 capsules contain the active substance colecalciferol, also known as vitamin D. 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 capsules are recommended for use when you have a normal intake of dietary calcium. Colextra-D3 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). Colextra-D3 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 Colextra-D3 capsules

Do not take Colextra-D3 capsules:

- If you are allergic (hypersensitive) to vitamin D or any of the other ingredients in the capsules (listed in Section 6)
- If you have high level 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 capsules:

- If you have kidney damage or disease. Your doctor may want to measure the level 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 Colextra-D3 capsules 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 capsules

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 capsules:

- Heart medicines (cardiac glycosides such as digoxin). Your doctor may monitor your heart with an electrocardiogram (ECG) and measure the level 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
- 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.

Driving and using machines

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

Colextra-D3 Capsules contains Sorbitol

This medicine contains 5.28 mg sorbitol in each capsule.

3. How to take Colextra-D3 capsules

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

(continued overleaf)

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Recommended Dose in Adults

Prevention of vitamin D deficiency	1 capsule every 4 weeks as directed by your doctor
In osteoporosis (you will also be taking other medicines for this)	1 capsule every 4 weeks as directed by your doctor
Treatment of vitamin D deficiency	Initial Dose 2 capsules weekly for 7 weeks as directed by your doctor
	Maintenance Dose 2 to 3 capsules monthly as directed by your doctor

The dose would be adjusted depending on the severity of the disease and the patient's response to the treatment.

Recommended Dose in Adolescents 12- 18 years of Age

Prevention of vitamin D deficiency	1 capsule every 6 weeks as directed by your doctor
Treatment of vitamin D deficiency:	1 capsule every 2 weeks for 6 weeks as directed by your doctor

Use in Children under 12 years of Age

Colextra-D3 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.

Method of administration

The capsules should be swallowed whole (not chewed) with water, preferably with the main meal of the day.

If you take more Colextra-D3 capsules than you should

If you accidentally take too many capsules 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 Colextra-D3 capsules

If you forgot to take a dose of Colextra-D3 capsules, take the forgotten dose as soon as possible. Then take the next dose at the correct time. 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. 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 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 capsules 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 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 capsules

Keep this medicine out of the sight and reach of children. This medicinal product does not require any special storage conditions.

Do not use Colextra-D3 capsules after the expiry date which is stated on the carton and blister 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 throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Colextra-D3 capsules contain

The active substance is colecalciferol.

Each capsule contains 20,000 IU colecalciferol (equivalent to 500 micrograms Vitamin D3)

The other ingredients are:

Capsule content:
triglycerides, medium chain all-rac- α -Tocopheryl acetate
Capsule shell:
gelatin, glycerol, sorbitol (E420), purified Water

Manufacturer

Cubic Pharmaceuticals Limited
Unit 3, Sextant Park,
Neptune Close,
Medway City Estate,
Rochester,
ME2 4LU, United Kingdom

Marketing Authorisation Holder

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

What Colextra-D3 capsules look like and contents of the pack

Colextra-D3 20,000 IU Capsule is a light yellow coloured transparent, round-shaped soft gelatin capsule containing a clear colourless liquid. Available in blister packs containing 10, 30 and 100 capsules. Not all pack sizes may be marketed.

This leaflet was last revised in April 2022

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