

Package leaflet: Information for the user

Coralium-D3 Forte Tablets

Read all of this leaflet carefully before you start using 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, or pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. See section 4

What is in this leaflet

1. What Coralium-D3 Forte Tablets is and what it is used for
2. What you need to know before you use Coralium-D3 Forte Tablets
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1. What Coralium-D3 Forte Tablets is and what it is used for

Coralium-D3 Forte Tablets contains calcium and vitamin D3 with multi-mineral and anti-oxidant supplement. They contain a combination of 9 essential vitamins, minerals and trace elements. The human body requires a wide variety of vitamins, minerals and trace elements to perform crucial daily tasks such as releasing energy from food and repairing cell damage. During certain illnesses, your body either cannot get or cannot efficiently use all of the vitamins, minerals and trace elements it needs. Your doctor, dietician or pharmacist will give you Coralium-D3 Forte Tablets if your diet has not provided you with enough vitamins, minerals and trace elements.

Coralium-D3 Forte Tablets is recommended for the prevention and treatment of deficiency of calcium and vitamin D3 which are essential for bone formation and normal bone metabolism. Each capsule contains the following 9 essential vitamins, minerals and trace elements, each of which plays a vital role in the efficient daily maintenance of many body processes.

Each tablet contains:

Coral calcium (elemental Calcium)500mg
Magnesium (elemental).....75mg

As Magnesium carbonate
 L-Lysine HCL.....30mg
 Zinc (elemental).....12mg
 As zinc sulphate
 Manganese (elemental).....4mg
 As Manganese chloride
 Copper (elemental).....1.7mg
 As copper sulphate
 Boron.....1mg
 Selenium (elemental).....40mcg
 As Sodium selenite
 Vitamin D3.....400IU
 (from lichen source)

The functions of the vitamins found in Bevon capsule are:

Vitamin D3	Essential for bone formation and normal bone metabolism
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The main functions of the minerals and trace elements are:

Calcium	Calcium is necessary for the formation of bones and teeth and plays a vital role in cell function, muscle contraction and in the nervous system.
Magnesium	Magnesium is essential for the formation of bones and teeth, and for the release of energy from food
Lysine	Lysine is an essential amino acid that is primarily used for protein synthesis. Lysine has been shown to increase iron absorption.
Zinc	Zinc is required for growth and cell function, bone metabolism, taste, insulin production and the body's immune system which fights infection.
Manganese	Manganese helps the body to utilize calcium and potassium and maintain the structure of cells.
Copper	Is required for growth and forms part of enzymes involved in blood and bone formation
Boron	Boron might have beneficial effects on functions such as, calcium metabolism, bone formation, immunity, and the function of steroid hormones (including vitamin D).
Selenium	Selenium helps to protect the cells and lipids from free radical damage

2. What you need to know before you use Coralium-D3 Forte Tablets

Do not take Coralium-D3 forte tablets

- if you are allergic to active substances or any of the other ingredients of this medicine
- if you have kidney stones
- if you have kidney failure or severe renal impairment
- if you have calcium deposits in your kidneys (nephrocalcinosis).
- if you have excessive amounts of vitamin D in the blood
- if you have chronically increased calcium levels in your urine or elevated blood-calcium level
- if you have disturbed parathyroid hormone metabolism
- if you have sarcoidosis (an inflammatory disease of unidentified origin characterized by formation of cell agglomerates (lumps) in different locations
- if you are an immobilized patient with osteoporosis
- if you are taking thiazide diuretics (to treat high blood pressure)
- if you are taking cardiac glycosides (to treat heart conditions) such as digoxin
- if you are less than 18 years of age.
- if you suffer from hypercalcaemia (high level of calcium in the blood)

Warnings and precautions

Talk to your doctor or pharmacist before taking Coralium-D3 forte tablets

- if you have kidney disease or impaired kidney function
- if you have sarcoidosis (an inflammatory disease of unidentified origin characterized by formation of cell agglomerates (lumps) in different locations)
- if you are prone to the development of kidney stones
- if you are an immobilized patient with osteoporosis
- if you are pregnant or thinking of becoming pregnant
- if you are a smoker
- if you have, bone disease, malignancies or calcium disorders

Children and adolescents

Coralium-D3 forte tablets are not intended for use in children and adolescents.

Other medicines and Coralium-D3 forte tablets

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

Consult your doctor or pharmacist if you use:

- other medicines or food supplements containing vitamin D or calcium, because concomitant (accompanying) use of such products with Coralium-D3 forte tablets may lead to a significant elevation of blood calcium levels and cause adverse effects that may be harmful. During the treatment with Coralium-D3 forte tablets, do not use any other products containing vitamin D or calcium without medical advice.
- thiazide diuretics
- systemic (per os [oral] or injection) corticosteroids (anti-inflammatory drugs)
- cardiac glycosides (used for the treatment of cardiac [heart] failure)

- Phenytoin (used to treat epilepsy)

Take special care if you use:

- ion exchange resins such as cholestyramine or laxatives such as paraffin oil, as these medicines may reduce the gastrointestinal absorption of vitamin D.
- tetracycline containing preparations (antibiotics), as calcium carbonate may interfere with their absorption. Therefore, tetracycline preparations should be administered at least two hours before or four to six hours after using of Coralium-D3 forte tablets.
- bisphosphonate (used for the treatment of osteoporosis) or sodium fluoride is used concomitantly with Coralium-D3 forte tablets, these preparations should be administered at least three hours before using Coralium-D3 forte tablets.
- Rifampicin (a medicine for tuberculosis), phenytoin (a medicine for epilepsy) and barbiturates (medicines which are used for epilepsy or which help you sleep), as they may make vitamin D3 less effective.
- Quinolone (antibiotics), as calcium may interfere with its absorption. Quinolone antibiotics should be taken two hours before or six hours after intake of calcium.
- Estramustin (a medicine used in chemotherapy), thyroid hormones or medicines containing iron, zinc or strontium, as the amount absorbed may be reduced. They should be taken at least 2 hours before or after Coralium-D3 forte tablets.

Coralium-D3 film-coated tablets with food and drink

Oxalic acid (found in e.g. spinach, sorrel and rhubarb), phosphate and phytic acid (found in whole cereals) may inhibit calcium absorption. The patient should not take Coralium-D3 forte tablets within two hours after eating foods rich in oxalic acid, phosphate and phytic acid.

Pregnancy, breast-feeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

During pregnancy, the daily intake should not exceed 1500 mg of calcium and 600 IU (International Unit) vitamin D. In pregnant women, overdoses of calcium and vitamin D should be avoided as permanent hypercalcaemia is related to adverse effects on the developing foetus. During pregnancy, Coralium-D3 forte tablets should be used in the recommended doses only in cases of calcium and vitamin D3 deficiency. In other cases, the daily dose of Coralium-D3 forte tablets must not exceed one tablet per day.

Coralium-D3 forte tablets can be used during breast-feeding, but your doctor should be informed as calcium and vitamin D gets into the breast milk. This should be considered when giving additional vitamin D to the child.

Driving and using machines

There is no data on the effect of this product on the ability to drive or use machines.

3. How to take Coralium-D3 Tablets

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose for adults and the elderly: one tablet per day or as directed by the doctor.

In pregnancy and lactation- should be given as per recommendation of doctor.

It is recommended to take the tablet within one and a half hours of a meal with a glass of water or juice, without chewing it. The tablet can be broken in half, if needed.

This tablet is not intended to diagnose, treat, cure or prevent any disease. This tablet is not to be used as a substitute for a varied diet

Use in children and adolescents

Coralium-D3 forte tablets are not intended for use in children and adolescents.

If you take more Coralium-D3 forte tablets than you should

Contact your doctor or pharmacist immediately if you have taken too much of this medicine. Remember to keep the pack and any remaining tablets with you.

Taking too much of this medicine may lead to symptoms such as lack of appetite, thirst, nausea, vomiting, constipation, abdominal pain, muscle weakness, fatigue, mental disturbances, excess drinking and excess urination, bone pain, calcification of the kidneys and in severe cases cardiac arrhythmias (irregular heartbeat). In extreme cases, calcium overdose can lead to coma and death. Long-term increased calcium levels in the blood may also lead to irreversible kidney impairment and calcification of soft tissues.

If you forget to take Coralium-D3 forte tablets

Do not take a double dose to make up for a forgotten dose, as you would not substitute the missing amount but you risk overdosing.

Continue the treatment according to the instructions.

If you have any further questions about 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. Adverse reactions are listed below by classes of organ systems and frequency of occurrence.

Frequency is defined as

- Uncommon (affects 1 to 10 users in 1,000)
- Rare (affects 1 to 10 users in 10,000)
- Very rare (affects less than 1 in 10,000)

Uncommon: significantly increased blood calcium level (hypercalcaemia)- the symptoms include nausea, vomiting, lack of appetite, constipation, stomach ache, bone pain, extreme thirst. Needing to pass urine more often, muscle weakness, drowsiness and confusion; or markedly increased calcium content of the urine (hypercalciuria).

Rare: constipation, flatulence (wind), nausea, abdominal pain, diarrhoea, itching, rash and urticaria (hives).

Very rare: dyspepsia (indigestion), Milk alkali syndrome (usually only seen in overdose).

Not known: Allergic reactions – symptoms include itching, wheezing, rash, and swelling of the tongue or throat. **If you have an allergic reaction stop taking the tablets and seek medical attention immediately.**

If you have impaired renal function, you may be at risk of increased amounts of phosphate in the blood, renal stone formation and increased amounts of calcium in the kidneys.

Reporting of side effects

- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly: Website: www.zuventus.co.in and click the tab “Safety Reporting” located on the top of the home page.
- By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Coralium-D3 forte tablets

Keep out of the reach and sight of children. Do not take Coralium-D3 forte tablets after the expiry date which is stated on the carton. The expiry date refers to the last day of that month after EXP.

Store in a cool and dry place at a temperature not exceeding 30°C. Keep the blister in the outer carton in order to protect from light.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist on how to dispose of medicines no longer required. These measures will help protect the environment.

6. Contents of the pack and other information

What Coralium-D3 forte tablets contains.

Each tablet contains:

Coral Calcium, Magnesium carbonate, L-Lysine HCL, zinc sulphate, Manganese chloride, copper sulphate, Boron, Sodium selenite and Vitamin D3 (from lichen source).

What Coralium-D3 forte tablets looks like and contents of the pack

Packaging: 10 tablets per pack

Marketing Authorisation Holder

Zuventus Healthcare Limited
Zuventus House, Plot Y2, CTS No.: 358/A2,
Near Nahur Railway Station,
Nahur (W), Mumbai, 400078 Maharashtra, India

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