

Package leaflet: Information for the user

Accrete® D3 Film-Coated Tablets

Calcium, Colecalciferol



Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after one month.

What is in this leaflet

1. What Accrete D3 film-coated tablet is and what it is used for
2. What you need to know before you take Accrete D3 film-coated tablets
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1. WHAT ACCRETE D3 FILM-COATED TABLET IS AND WHAT IT IS USED FOR

The product is a combination of calcium (as calcium carbonate) and colecalciferol (Vitamin D3).

It is recommended in the elderly for the prevention and treatment of deficiency of calcium and vitamin D3 that are essential for bone formation and normal bone metabolism. It is also recommended for use as a Vitamin D and calcium supplement alongside specific osteoporosis treatments in people who are at risk of vitamin D and calcium deficiency.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ACCRETE D3 FILM-COATED TABLETS

Do not take Accrete D3 film-coated tablets

- if you are allergic to active substances or any of the other ingredients of this medicine (listed in section 6)
- Accrete D3 film-coated tablets contain hydrogenated soya oil. If you are allergic to peanut or soya, do not use this medicinal product.
- 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 level 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 immobilised 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

Warnings and precautions

Talk to your doctor or pharmacist before taking Accrete D3 film-coated 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 development of kidney stones
- if you are an immobilised patient with osteoporosis

Children and adolescents

Accrete D3 film-coated tablets are not intended for use in children and adolescents.

Other medicines and Accrete D3 film-coated 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 Accrete D3 film-coated tablets

may lead to a significant elevation of blood-calcium levels and cause adverse effects that may be harmful. During the treatment with Accrete D3 film-coated 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)

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 Accrete D3 film-coated tablets.
- bisphosphonate (used for the treatment of osteoporosis) or sodium fluoride is used concomitantly with Accrete D3 film-coated tablets, these preparations should be administered at least three hours before using Accrete D3 film-coated 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 the 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 Accrete D3 film-coated tablets.

Accrete 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 Accrete D3 film-coated 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 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.

During pregnancy, the daily intake should not exceed 1500 mg 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, Accrete D3 film-coated tablets should be used in the recommended doses only in cases of calcium and vitamin D₃ deficiency. In other cases the daily dose of Accrete D3 film-coated tablets must not exceed one tablet per day. Accrete D3 film-coated 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. There are no data available on the effect of Accrete D3 film-coated tablets on fertility.

Driving and using machines

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

Accrete D3 film-coated tablets contain soya oil and sucrose

Accrete D3 film-coated tablets contain hydrogenated soya oil. If you are allergic to peanut or soya, do not use this medicinal product.

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Accrete D3 film-coated tablets contain sucrose. 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 ACCRETE D3 FILM-COATED 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 is one film-coated tablet 2 times per day (e.g. one tablet in the morning and one tablet in the evening).

It is recommended to take the film-coated 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.

Use in children and adolescents

Accrete D3 film-coated tablets are not intended for use in children and adolescents under 18 years.

If you take more Accrete D3 film-coated 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 Accrete D3 film-coated 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 an overdosing. Continue the treatment according to the instructions.

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. 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, 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 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 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 ACCRETE D3 FILM-COATED TABLETS

Do not store above 25°C. Store in the original package in order to protect from moisture. Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton (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 Accrete D3 film-coated tablets contain

- The active substances: Colecalciferol 400IU (equivalent to 10 micrograms) and calcium 600 mg (as calcium carbonate 1500 mg) in each film-coated tablet.
- The other ingredients:
Tablet core: magnesium stearate, crospovidone (Type A), copovidone (K-value: 25.2-30.8), microcrystalline cellulose, sucrose, gelatin, all-rac-a-tocopherol (E307), hydrogenated soya-bean oil, maize starch.

Coating: yellow iron oxide (E172), hypromellose (15 mPa s), titanium dioxide (E171), macrogol 3350, talc.

What Accrete D3 film-coated tablets look like and contents of the pack

Ochre, oval shaped, film-coated tablets scored on one side. When broken the exposed surface is white. The score line is only to facilitate breaking for ease of swallowing and not to divide into equal halves.

10 film-coated tablets in transparent, colourless PVC/Alu blister and 3 or 6 blisters in cardboard box. Not all pack sizes may be marketed.

Marketing Authorisation Holder

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