

Package leaflet: Information for the user

Colecalciferol Aristo 20,000 IU soft capsules colecalciferol (vitamin D3)

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

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

Colecalciferol Aristo Capsules contains colecalciferol (vitamin D3).

Vitamin D is found in some foods and is also produced in the body when skin is exposed to sunlight.

Vitamin D helps the kidneys and intestine absorb calcium and it helps build bones.

Colecalciferol Aristo Capsules are used for initial treatment of symptomatic vitamin D deficiency in adults.

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

Do not take Colecalciferol Aristo Capsules:

- if you are allergic to colecalciferol or any of the other ingredients of this medicine (listed in section 6)
- if you have high levels of calcium in your blood (hypercalcaemia) or urine (hypercalciuria)
- if you have a condition which means that your body is resistant to parathyroid hormone (pseudohypoparathyroidism)
- if you have high levels of vitamin D in your blood (hypervitaminosis D)
- if you have kidney stones, calcification of the kidneys or serious kidney problems.

Warnings and precautions

Talk to your doctor or pharmacist before taking Colecalciferol Aristo Capsules if you:

- are undergoing treatment with certain medicines used to treat heart disorders (e.g. diuretics, cardiac glycosides such as digoxin)
- have sarcoidosis (an immune system disorder which may cause increased levels of vitamin D in the body)
- are immobilised
- are taking medicines containing vitamin D, or eating foods or milk enriched with vitamin D
- are likely to be exposed to a lot of sunlight whilst using Colecalciferol Aristo Capsules

- take additional supplements which contain calcium or you take medicines or have a condition that can alter your calcium or phosphate levels. Your doctor will monitor your blood levels of calcium to make sure they are not too high whilst you are using Colecalciferol Aristo Capsules
- have kidney damage or disease. Your doctor may want to measure the levels of calcium in your blood or urine
- have a tendency to form calcium-containing kidney stones.

Children and adolescents

Colecalciferol Aristo Capsules are not indicated for use in children and adolescents.

Other medicines and Colecalciferol Aristo Capsules

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

This is especially important if you are taking:

- medicines that act on the heart or kidneys, such as cardiac glycosides (e.g. digoxin) or diuretics (e.g. bendroflumethazide). When used at the same time as vitamin D these medicines may cause a large increase in the level of calcium in the blood and urine. Your doctor may monitor your heart with an electrocardiogram (ECG) and measure the levels of calcium in your blood
- actinomycin (a medicine used to treat some forms of cancer) and imidazole antifungals (e.g. clotrimazole and ketoconazole, medicines used to treat fungal disease). These medicines may interfere with the way your body processes vitamin D
- the following medicines because they can interfere with the effect or the absorption of vitamin D:
 - antiepileptic medicines (anticonvulsants such as phenytoin)
 - medicines that alter your nervous system (sedatives such as barbiturates)
 - glucocorticoids (steroid hormones such as hydrocortisone or prednisolone). These can decrease the effect of vitamin D
 - medicines that lower the level of cholesterol in the blood (such as cholestyramine, or colestipol)
 - certain medicines for weight loss that reduce the amount of fat your body absorbs (e.g. orlistat)
 - certain laxatives (such as liquid paraffin)
 - antibiotics used to treat the bacterial infection called tuberculosis (TB) (e.g. rifampicin and isoniazid) as they may reduce the effectiveness of vitamin D.

Colecalciferol Aristo Capsules with food and drink

You should take Colecalciferol Aristo Capsules with a large meal to help your body absorb the 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. This high strength formulation is not recommended for use in pregnant and breastfeeding women.

Driving and using machines

There is limited information on the possible effects of this medicine on your ability to drive. However, it is not expected that it would affect your ability to drive or operate machinery.

Colecalciferol Aristo Capsules contain Sorbitol

This medicine contains 16.5 mg sorbitol in each capsule.

3. How to take Colecalciferol Aristo Capsules

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

Adults

The recommended dose is 1 capsule per week during the first month, your doctor will adjust the dose for you.

Use in pregnancy and breast-feeding

This high strength formulation is not recommended.

Use in children and adolescents

Colecalciferol Aristo Capsules are not suitable for children or adolescents.

Method of administration

You should swallow the capsules whole with water, do not chew the capsules.

If you take more Colecalciferol Aristo Capsules than you should

If you take more medicine than prescribed, stop taking this medicine and contact your doctor. If it is not possible to talk to your doctor go to the nearest hospital emergency department and take the medicine package with you. The most common symptoms of overdose are: feel or be sick (nausea & vomiting), excessive thirst, production of large amounts of urine over 24 hours, constipation and dehydration, high levels of calcium in the blood and urine (hypercalcaemia and hypercalciuria) shown by lab tests.

If you forget to take Colecalciferol Aristo Capsules

If you forgot to take a dose of Colecalciferol Aristo 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 Colecalciferol Aristo Capsules may include:

Uncommon (may affect up to 1 in 100 people):

- too much calcium in your blood (hypercalcaemia)
- too much calcium in your urine (hypercalciuria).

Rare (may affect up to 1 in 1,000 people):

- skin rash

- itching
- hives.

Not known (we do not know how often these happen):

- altered bowel movements
- wind
- feeling sick (nausea)
- stomach pain.

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 HPRA Pharmacovigilance, Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Colecalciferol Aristo Capsules

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

Store below 25°C.

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 Aristo Capsules contains

- The active substance is colecalciferol (vitamin D3). Each capsule contains 500 microgram colecalciferol (vitamin D3, equivalent to 20,000 IU).
- The other ingredients are:

Capsule: medium chain triglycerides and all-rac- α -Tocopheryl acetate.

Capsule shell: gelatin, glycerol, sorbitol liquid partially dehydrated (E420) and purified water.

What Colecalciferol Aristo Capsules looks like and contents of the pack

Colecalciferol Aristo Capsules are light yellow coloured, clear transparent round shaped gelatin capsules with a clear, colourless liquid fill.

It is available in blister strips containing of 4, 6, 14 and 50 or hospital pack of 56 (4x14) capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Aristo Pharma GmbH
Wallenroder Straße 8-10
13435 Berlin
Germany

This medicinal product is authorised in the Member States of the EEA under the following names:

Ireland: Colecalciferol Aristo 20,000 IU soft capsules
Germany: Colecalciferol Aristo 20.000 I.E. Weichkapseln

This leaflet was last revised in 06/2022.