PACKAGE LEAFLET: INFORMATION FOR THE USER

altavitaD3 1,000 IU soft capsules
altavitaD3 7,000 IU soft capsules
colecalciferol (vitamin D3)

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 ALTAVITAD3 IS AND WHAT IT IS USED FOR

altavitaD3 contains colecalciferol (vitamin D3). Vitamin D can be found in some foods and is also produced by the body when skin is exposed to sunlight. Vitamin D3 helps the kidneys and intestine absorb calcium and it helps build bones.

altavitaD3 is used:

- to prevent vitamin D deficiency when there is a significant risk of deficiency or an increased demand for vitamin D
- with other medicine to treat certain bone conditions, such as thinning of the bone (osteoporosis).
- to treat vitamin D deficiency that has been confirmed by laboratory tests.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ALTAVITAD3

Do not take altavitaD3:

- if you are allergic to vitamin D 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 kidney stones (renal calculi);
- if you have high levels of vitamin D in your blood (hypervitaminosis D)

If any of the above applies to you, talk to your doctor or pharmacist before taking altavitaD3..

Warnings and precautions

Talk to your doctor or pharmacist before taking altavitaD3 if you:

- are undergoing treatment with certain medicines used to treat heart disorders (e.g. cardiac glycosides, such as digoxin);
- have sarcoidosis (an immune system disorder which may cause increased levels of vitamin D in the body);
- are taking medicines containing vitamin D, or eating foods or milk enriched with vitamin D;
- are likely to be exposed to a lot of sunshine whilst using altavitaD3;
- take additional supplements containing calcium. Your doctor will monitor your blood levels of calcium to make sure they are not too high whilst you are using altavitaD3;
- have kidney damage or disease. Your doctor may want to measure the levels of calcium in your blood or urine.

Children
This medicine is not suitable for use in children under 10 years of age.

Other medicines and altavitaD3

Tell your doctor or pharmacist if you are using, have recently used or might use 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;
- medicines containing vitamin D or eating food rich in vitamin D, such as, some types of vitamin D-enriched milk;
- 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 process vitamin D;
- the following medicines because they can interfere with the effect or the absorption of vitamin D:
    - antiepileptic medicines (anticonvulsants), 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).

altavitaD3 with food and drink
See section 3 “How to take altavitaD3”

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.

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 to operate machinery.

altavitaD3 contains Allura Red AC (E129) and Sunset Yellow FCF (E110)

altavitaD3 1,000 IU, soft capsules contain Allura Red AC (E129) which may cause allergic reactions.

altavitaD3 7,000 IU soft capsules contain Sunset Yellow FCF (E110) which may cause allergic reactions.

If you are allergic to the above colouring agents, consult your doctor or pharmacist.

3. HOW TO TAKE ALTAVITAD3

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

The capsules should be swallowed whole with water.

You should take this altavitaD3 preferably together with a large meal to help your body absorb the vitamin D3.

Dosage

1,000 IU soft capsules
Your doctor will usually prescribe these soft capsules daily.
7,000 IU soft capsules
Your doctor will usually prescribe these soft capsules weekly.

Use in adults
The recommended dose for:

Prevention of vitamin D deficiency: 1,000 IU/day
Treatment of vitamin D deficiency: 1,000 IU – 4,000 IU/day for up to 12 weeks, followed by maintenance therapy of 1,400 IU – 2,000 IU/day (such as two 1,000 IU soft capsules per day or two 7,000 IU soft capsules per week).
Addition to specific therapy for osteoporosis: 1,000 IU/day

Use in children and adolescents
The recommended dose for:
- **Prevention of deficiency 10-18 years**: doses of up to 1,000 IU/day may be required to prevent deficiency in some children.
- **Treatment of deficiency 10-18 years**: 2,000 IU/day for 6 weeks, followed by a maintenance therapy of 400 IU-1,000 IU/day (such as one 1,000 IU soft capsule per day or one 7,000 IU soft capsule per week).

Use in pregnancy and breast-feeding
The recommended dose for:

<u>Prevention</u> of deficiency:

Doses of 1,000 IU – 2,000 IU /day may be required to prevent deficiency in some women

Even higher doses may be required in breast-feeding if women choose not to give the infant a vitamin D supplement.

If you take more altavitaD3 than you should

If you or your child take more medicine than prescribed, stop using this medicine and contact your doctor. If it is not possible to talk to a doctor go to the nearest hospital emergency department and take the medicine package with you.

The most common symptoms of overdose are: nausea, vomiting, excessive thirst, the production of large amounts of urine over 24 hours, constipation and dehydration, high levels of calcium in the blood (hypercalcaemia and hypercalciuria) shown by lab test.

If you forget to take altavitaD3
If you forget to take a dose of altavitaD3, 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.

If you stop taking altavitaD3
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.
Possible side effects 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

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 ALTAVITAD3

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 after "Exp". The expiry date refers to the last day of that month.

Do not store above 25°C.

Store in the original packaging in order to protect from light.

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 altavitaD3 contains

- The active substance is colecalciferol (vitamin D3).

  altavitaD31,000 IU soft capsules

  Each capsule contains 1,000 IU of colecalciferol (vitamin D3) equivalent to 0.025 mg.

- The other ingredients are: all-rac-α-tocopherol (E307), medium chain triglycerides, glycerol, gelatine, Opacode® White imprinting ink (consisting of: shellac (E904), titanium dioxide (E171) and simethicone), Allura Red AC (E129).

  altavitaD3 7,000 IU soft capsules

  Each capsule contains 7,000 IU of colecalciferol (vitamin D3) equivalent to 0.175 mg.

- The other ingredients are: all-rac-α-tocopherol (E307), medium chain triglycerides, glycerol, gelatine, Opacode® White imprinting ink (consisting of: shellac (E904), titanium dioxide (E171) and simethicone), Sunset Yellow FCF (E110).

What altavitaD3 looks like and contents of pack

altavitaD31,000 IU soft capsules

altavitaD3 1,000 IU is a dark red , oval-shaped, soft capsule. It contains a slightly yellow oily liquid. Each capsule has "1" printed in white ink.

Each carton contains 28 capsules in blister strips.

altavitaD3 7,000 IU soft capsules

altavitaD3 7,000 IU is a yellow, oval-shaped, soft capsule. It contains a slightly yellow oily liquid. Each capsule has "7" printed in white ink.

Each carton contains 4 capsules in blister strips.

Marketing Authorisation Holder:

Consilient Health Limited
Floor 3, Block 3, Miesian Plaza,

Dublin 2, D02 Y754,
Ireland.

Manufacturers:

Consilient Health Limited,
Block 2A Richview Office Park,
Clonskeagh, Dublin 14,
D14 Y0A5, Ireland

This medicinal product is authorised in the following member states of the EEA under the following names:

Ireland:	altavitaD3 1,000 IU soft capsules altavitaD3 7,000 IU soft capsules
United Kingdom:	InVita D3 1,000 IU soft capsules InVita D3 7,000 soft capsules

This leaflet was last revised in January 2024.