PACKAGE LEAFLET: INFORMATION FOR THE USER

altavita D3 800 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 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 vitamin D3 which regulates the uptake and metabolism of calcium as well as the incorporation of calcium in bone tissue.

altavitaD3 is used to prevent and treat vitamin D3 deficiency in adults and adolescents.

Your doctor may prescribe altavitaD3 as an adjunct to specific bone loss medication.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ALTAVITAD3

Do not take altavitaD3:

- if you are allergic to colecalciferol or any of the other ingredients of this medicine (listed in section 6).
- if you have hypercalcaemia (increased levels of calcium in the blood) or hypercalciuria (increased levels of calcium in the urine).
- if you have hypervitaminosis D (increased levels of vitamin D in the blood).
- if you have kidney stones.

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 suffer from sarcoidosis (a special type of connective tissue disease that affects the lungs, skin and joints).
- when using other drugs containing vitamin D.

- if you have kidney problems or have had kidney stones.

Children
This medicine is not recommended for use in children under 12 years of age.

Other medicines and altavitaD3

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, in particular any of the following:

- Cholestyramine (used to treat high cholesterol).

- Phenytoin or barbiturates (used to treat epilepsy).

- Laxatives which contain paraffin oil.

- Thiazide diuretics (to treat high blood pressure).

- Glucocorticoids (to treat inflammation).

- Cardiac glycosides (to treat heart conditions), e.g. digoxin.

- Actinomycin (chemotherapy)

- Imidazole (antifungal)

- Orlistat (weight loss aid)

altavitaD3 with food and drink

See section 3 “How to take altavitaD3”.

Pregnancy, breast-feeding and fertility

During pregnancy the daily intake should not exceed 600 IU vitamin D.

altavitaD3 should only be used during pregnancy, if vitamin D deficiency has been clinically established.

altavitaD3 can be used during breastfeeding. Vitamin D3 passes over into breast milk. This should be considered when giving additional vitamin D to the breast-fed child.

Ask your doctor or pharmacist for advice before taking altavitaD3 during pregnancy, if you are breast feeding or if you are planning to have a baby.

Driving and using machines

altavitaD3 has no known effects on ability to drive or use machines.

altavitaD3 contains Allura Red AC (E129)

altavitaD3 800 IU soft capsules contain Allura Red AC (E129) which may cause allergic reactions.

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

3. HOW TO TAKE ALTAVITAD3

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

The capsules should be swallowed whole with water.
altavitaD3 can be taken with or without food.

The recommended dose is: 1 capsule every day.
The daily dose shall not exceed 5 capsules.

Use in children

altavitaD3 800 IU capsules are not intended for use in children under 12 years of age. Other forms of this medicine maybe more suitable for children; ask your doctor or pharmacist.

If you take more altavitaD3 than you should

If you have taken more of this medicine than directed, or if a child accidentally has taken this medicine, please contact your doctor or emergency unit for judgement of the risk and advice.

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

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.

Stop taking altavitaD3 and seek immediate medical help if you experience symptoms of serious allergic reactions, such as:

- swollen face, lips, tongue or throat
- difficulty swallowing
- hives and difficulty breathing

Uncommon (may affect up to 1 in 100 people): Hypercalcaemia (increased levels of serum calcium) and hypercalciuria (increased levels of urine calcium).

Rare (may affect up to 1 in 1,000 people): Itching, rash (Pruritus/urticaria).

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
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@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 and blister after Exp. The expiry date refers to the last day of the month.

Do not store above 25°C. Keep the blister(s) in the outer carton 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). Each soft capsule contains 0.02 mg colecalciferol corresponding to 800 IU vitamin D3.

- 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).

What altavitaD3 looks like and contents of the pack

altavitaD3 800 IU is a pink, oval-shaped, soft capsule. It contains a slightly yellow oily liquid. Each capsule has “0.8” printed in white ink. Capsule dimensions are 10.5mm x 7mm.

altavitaD3 800 IU is available in boxes of 28 or 90 capsules packed in blister strips.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Consilient Health Limited.
5th Floor, Beaux Lane House,
Mercer Street Lower,

Dublin 2
Ireland

Manufacturers:

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

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

Netherlands: Colecalciferol Benferol 800 IE zachte capsules
United Kingdom: InVita D3 800 IU soft capsules
Ireland: altavitaD3 800 IU soft capsules
Spain: Benferol D3 800 UI cápsulas blandas
Denmark: Benferol
Finland: Benferol
Norway: Benferol
Sweden: Benferol

This leaflet was last revised in May 2022