160 mm

40 mm

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240 mm

PACKAGE LEAFLET: INFORMATION FOR THE USER

InVita D3 5,600 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 InVita D3 is and what it is used for
2. What you need to know before you take InVita D3
3. How to take InVita D3
4. Possible side effects
5. How to store InVita D3
6. Contents of the pack and other information

1. WHAT INVITA D3 IS AND WHAT IT IS USED FOR

InVita D3 contains vitamin D3 which regulates the uptake and metabolism of calcium as well as the incorporation of calcium in bone tissue.
InVita D3 is used to prevent and treat vitamin D3 deficiency in adults and adolescents.
Your doctor may prescribe InVita D3 as an adjunct to specific bone loss medication.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE INVITA D3

Do not take InVita D3:
- 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 InVita D3.

Warnings and precautions
Talk to your doctor or pharmacist before taking InVita D3:
- 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 InVita D3
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)

InVita D3 with food and drink
See section 3 “How to take InVita D3”.

Pregnancy and breast-feeding:
InVita D3 can be used up to 2 capsules a week during pregnancy, only if you have been diagnosed with vitamin D deficiency and following the advice of your doctor.

InVita D3 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 InVita D3 during pregnancy, if you are breast feeding or if you are planning to have a baby.

Driving and using machines
InVita D3 has no known effects on ability to drive or use machines.

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ARTWORK SPECIFICATION	FONTS	COLOURS	DESIGNED BY
Client : Consilient Health Ltd.	Helvetica Neue Lt Std	Black	Minty
Project : Dec 2023	Globale		
Item(s) : InVita D3 5,600 IU soft capsules			
Size : 160 x 240 mm			
Software : InDesign CC			

160 mm

40 mm

60 mm

240 mm

InVita D3 contains Allura Red AC (E129) and Sunset Yellow FCF (E110)
InVita D3 5,600 IU soft capsules contain Allura Red AC (E129) and 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 INVITA D3

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. InVita D3 can be taken with or without food.

The recommended dose is: 1 capsule every week.
The weekly dose shall not exceed 5 capsules.

Use in children
InVita D3 5,600 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 InVita D3 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 in the urine (hypercalciuria) shown by lab test.

If you forget to take InVita D3
Do not take a double dose to make up for a forgotten dose.

If you stop taking InVita D3
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 InVita D3 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 the Yellow Card Scheme Website: 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 INVITA D3

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. Store in the original packaging to protect from light. Shelf life after first opening is 2 months. Plastic bottle only: Shelf life after first opening is 2 months.
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 InVita D3 contains
- The active substance is colecalciferol (vitamin D3). Each soft capsule contains 0.14 mg colecalciferol corresponding to 5,600 IU vitamin D3.
- The other ingredients are: all-rac-⊠-tocopherol (E307), medium chain triglycerides,glycerol (E422), gelatin (E441), Purified water, Opacode® White imprinting ink (consisting of: Shellac (E904), Titanium dioxide (E171), Ammonium hydroxide (E527), Propylene Glycol (E1520), N-butyl alcohol, Isopropyl alcohol and simethicone), Allura Red AC (E129) and Sunset Yellow FCF (E110).

What InVita D3 looks like and contents of the pack
InVita D3 5,600 IU is a red, oval-shaped, soft capsule. It contains a slightly yellow oily liquid. Each capsule has “5.6” printed in white ink.
Each carton contains 4 or 12 capsules packed in blisters or 250 capsules packed in a plastic bottle.
Not all pack sizes may be marketed.

Marketing Authorisation Holder:
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Dublin 2, D02 Y754, Ireland.

Manufacturer:
Consilient Health (UK) Ltd.,
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