PACKAGE LEAFLET: INFORMATION FOR THE USER

InVita D3 25,000 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 pharmacist or nurse. This includes any possible any 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 colecalciferol (vitamin D3). Vitamin D3 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.

InVita D3 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 INVITA D3

Do not take InVita D3:

- if you are allergic to vitamin D3 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 serious renal impairment
- if you have high levels of vitamin D3 in your blood (hypervitaminosis D)
- if you have pseudohypoparathyroidism (disturbed parathyroid hormone metabolism)
- if you are pregnant

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:

- 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 D3 in the body);
- are taking medicines containing vitamin D3, or eating foods or milk enriched with vitamin D3;
- are likely to be exposed to a lot of sunshine whilst using InVita D3;
- 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 InVita D3;
- 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 and adolescents under 10 years of age.

Other medicines and InVita D3

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 D3 these medicines may cause a large increase in the level of calcium in the blood and urine;
- medicines containing vitamin D3 or eating food rich in vitamin D3, such as, some types of vitamin D3-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 D3;
- the following medicines because they can interfere with the effect or the absorption of vitamin D3:
  - antiepileptic medicines (anticonvulsants), barbiturates,
  - glucocorticoids (steroid hormones such as hydrocortisone or prednisolone). These can decrease the effect of vitamin D3;
  - 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).

InVita D3 with food and drink

See section 3 “How to take InVita D3”.

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.

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 to operate machinery.

InVita D3 contains Allura Red AC (E129)

InVita D3 25,000 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 INVITA D3

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 InVitaD3 preferably together with a large meal to help your body absorb the vitamin D.

Use in children and adolescents

The recommended dose for:

- **Prevention of deficiency 10-18 years**: 25,000 IU (1 capsule) every 6 weeks
- **Treatment of deficiency 10-18 years**: 25,000 IU (1 capsule) once every 2 weeks for 6 weeks (followed by maintenance therapy of 400 IU – 1,000 IU/day, such as 1 capsule a month.)

Use in pregnancy and breast-feeding
This high strength formulation is not recommended

Use in adults
The recommended dose for:
Prevention of vitamin D deficiency: 25,000 IU/month (1 capsule)

Addition to specific therapy for osteoporosis: 25,000 IU/month (1 capsule)

Treatment of vitamin D deficiency: 50,000 IU/week (2 capsules) for 6-8 weeks, followed by maintenance therapy (1,400- 2,000 IU/day, such as 2 capsules a month.)

If you take more InVita D3 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 InVita D3
If you forget to take a dose of InVita D3, 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 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.

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 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 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 InVita D3 contains

- The active substance is colecalciferol (vitamin D3).
  Each capsule contains 25,000 IU of colecalciferol (vitamin D3) equivalent to 0.625 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).

What InVita D3 looks like and contents of pack

InVita D3 25,000 IU is a light red, oval-shaped, soft capsule. It contains a slightly yellow oily liquid. Each capsule has “25” printed in white ink.

Each carton contains 3 capsules packed in blister strips.

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