PACKAGE LEAFLET:
INFORMATION FOR THE USER

InVita D3®
2,400 IU/ml oral drops, solution
Colecalciferol

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 or pharmacist, or nurse.
- This medicine has been prescribed for you only. Do not pass it onto 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 use InVita D3
3. How to use 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 oral drops contain colecalciferol (vitamin D). Vitamin D can be found in some foods and is also produced by the body when skin is exposed to sunlight. Vitamin D helps the kidneys and intestine absorb calcium and it helps build bones.
InVita D3 oral drops are used:
- to prevent vitamin D deficiency when there is a significant risk of deficiency or an increased demand for vitamin D

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

Do not use InVita D3
- 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).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before using 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 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 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.

Other medicines and InVita D3
Tell your doctor or pharmacist if you are using or 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 processes 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).

InVita D3 with food, drink and alcohol
You should take this medicine preferably together with a large meal to help your body absorb the vitamin D. You can also mix the drops with cold or lukewarm food, to help you take this medicine. For detailed information see section 3 “How to use 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. InVita D3 should be used during pregnancy and breast-feeding only if recommended by your doctor.

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.

3. HOW TO USE 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.
1 drop contains 67 IU vitamin D.
Shake before use.
You should take InVita D3 preferably together with a large meal. This medicine can be taken on its own or you can mix the prescribed number of drops with a spoonful or a small amount of cold or lukewarm food immediately before use. Make sure the entire dose is taken.

Use in children and adolescents
The recommended dose for:
- Prevention of deficiency 0-1 years: **400 IU/day (6 drops)**
- Prevention of deficiency 1-18 years: **600 IU/day (9 drops)**

In children, InVita D3 can be mixed with a small amount of children's foods, yogurt, milk, cheese or other dairy products. Do not mix this medicine into a bottle of milk or container of soft food, in case your child does not consume the whole portion, and does not receive the full dose. You should make sure that the entire dose is taken. For children who are not being breast-fed you should give the prescribed dose with a substantial meal.
Do not store any product or food mixture that contains InVita D3 for use at a later time or a next meal.

Use in pregnancy and breast-feeding
The recommended dose for:
- Prevention of deficiency: **400 IU/day (6 drops)**

If you take more InVita D3 than you should
If you or your child takes 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 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 reported with the use of InVita D3 may include:
Uncommon (affects less than 1 in 100 people)
- Too much calcium in your blood (hypercalcaemia)
- Too much calcium in your urine (hypercalciuria)

Rare (affects less than 1 in 1000 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 effect directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. 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 bottle after "Exp". The expiry date refers to the last day of that month.
Keep the bottle in the outer carton in order to protect from light.
After the first opening the bottle: the product may be stored for a maximum of 3 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 D).
1 ml solution (36 drops) contains 0.06 mg colecalciferol, equivalent to 2,400 IU vitamin D3.
1 drop contains 1.67 microgram colecalciferol, equivalent to 67 IU vitamin D3.

The other ingredients are sweet orange peel oil, all-rac-α-tocopheryl acetate, polyglyceryl oleate (E475) and refined olive oil.

What InVita D3 looks like and contents of pack
InVita D3 2,400 IU/ml oral drops, solution is a clear liquid with an orange odour. It is supplied in a 10 ml brown, molded glass bottles sealed with polypropylene screw cap. Each pack contains 1 brown, molded glass bottle containing 10 ml solution.

Marketing authorisation holder
Consilient Health Limited,
Floor 3, Block 3, Miesian Plaza,
Dublin 2, D02 Y754, Ireland.

Manufacturer
SMB Technology S.A.,
39, rue du Parc Industriel, 6900 Marche en Famenne,
Belgium.

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