invitaD3 25,000 IU oral solution
cocalecalciferol

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

1. WHAT invitaD3 IS AND WHAT IT IS USED FOR

invitaD3 is a vitamin product containing cocalecalciferol (equivalent to vitamin D3). Vitamin D can be found in some foods and 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.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE invitaD3

Do not use invitaD3
- if you are allergic to vitamin D or any of the other ingredients of invitaD3 (listed in section 6).
- if you have hypercalcemia (high levels of calcium in the blood).
- if you have hypercalcuria (high levels of calcium in the urine).
- if you have pseudoparathyroism (disturbed parathyroid hormone metabolism).
- if you have renal calculi (kidney stones).
- if you have hypervitaminosis D (high levels of vitamin D in the blood).

Warnings and precautions
- Tell your doctor, pharmacist or nurse before using invitaD3 if you:
  - are undergoing treatment with certain medicines used to treat heart conditions (e.g. cardiac glycosides, such as digoxin).
  - have certain conditions (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 invitaD3.
  - 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 invitaD3.
  - have kidney damage or disease. Your doctor may want to measure the levels of calcium in your blood or urine.

Other medicines and invitaD3
- 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.
  - medicines that act on the heart (cardiac glycosides, such as digoxin) or that control the heart rate (beta-blockers or beta-receptor blockers).
  - medicines that lower the level of cholesterol in the blood (such as cholestyramine, or colestipol).
  - medicines that act on the heart or kidneys (such as angiotensin-converting enzyme inhibitors).
  - medicines that act on the heart (such as angiotensin-converting enzyme inhibitors) or that reduce the amount of fat your body absorbs (e.g. orlistat).
  - medicines that lower the level of cholesterol in the blood (such as cholestyramine, or colestipol).
  - medicines for weight loss that reduce the amount of fat your body absorbs (e.g. orlistat).
  - certain laxatives (such as liquid paraffin).

invitaD3 with food, drink and alcohol
- You should take this medicine preferentially together with a large meal to help your body absorb the vitamin D. You can also mix the solution with cold or lukewarm food, to help you take this medicine.
- For detailed information see section 4. “How to use invitaD3”.

3. HOW TO USE invitaD3

Always take invitaD3 exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

You should take invitaD3 preferably together with a large meal.

This medicine has a delicate taste of olive oil. The contents of the single-dose oral solution is to be emptied directly into the mouth and swallowed orally as per the diagram below.

4. POSSIBLE SIDE EFFECTS

The possible side effects (adverse reactions) may include:

- an increased demand for vitamin D.
- decreased effect of vitamin D.
- high levels of calcium in the blood.

These are symptoms when using the high strength form of the medicine.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

5. HOW THE BODY ABSORBS invitaD3

invitaD3 helps the kidneys and intestine absorb calcium and it helps build bones.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

For detailed information see section 6. “Contents of the pack and other information”.
To help you take this medicine, the full contents of the single-dose oral solution may be emptied onto a spoon and taken orally. You may also mix the contents of the single-dose oral solution with 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 is:

• Prevention of vitamin D deficiency in 0-1 years:
  1 single-dose oral solution of invitaD3 25,000 IU every 6 weeks.

• Prevention of vitamin D deficiency in 1-18 years:
  1 single-dose oral solution of invitaD3 25,000 IU every 6 weeks.

• Treatment of vitamin D deficiency in 1-18 years:
  1 single-dose oral solution of invitaD3 25,000 IU once every 2 weeks for 6 weeks (followed by maintenance therapy of 400-1000 IU/day, such as 25,000 IU (1 single-dose oral solution) monthly).

In children, invitaD3 can be mixed with a small amount of children’s foods, yoghurt, milk, 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 no longer being breast fed you should give the prescribed dose with a substantial meal.

Do not store any product or food mixture that contains invitaD3 for use at a later time or a next meal.

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

Use in adults
The recommended dose is:

• Prevention of vitamin D deficiency:
  1 single-dose oral solution of invitaD3 25,000 IU per month. Higher doses may be required based on the advice of your doctor.

• Addition to specific therapy for osteoporosis:
  Triangle-dose oral solution of invitaD3 25,000 IU per month.

• Treatment of vitamin D deficiency:
  2 single-dose oral solutions of invitaD3 25,000 IU once weekly for 6-8 weeks, followed by maintenance therapy (400-2000 IU/day such as 50,000 IU (1 single-dose oral solution) per month) may be required, based on the advice of your doctor.

If you take more than invitaD3 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 invitaD3
If you forget to take a dose of invitaD3, 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 may include:

Uncommon (may affect up to 1 in 100 people)
• Too much calcium in your blood (hypercalcemia)
• Too much calcium in your urine (hypercalciuria)

Rare (may affect up to 1 in 10,000 people)
• Itching
• Skin rash
• Acne
• Bones
• Nausea

Uncommon (may affect up to 1 in 100 people)
• Skin rash
• Acne
• Bones
• Nausea

Reporting of side effects:
If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects listed in this leaflet, or if you think there may be side effects not already listed in this leaflet. Reporting of side effects:

• Skin rash
• Acne
• Bones
• Nausea

Keep this medicine out of the sight and reach of children.

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.

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If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

5. HOW TO STORE INVITAD3
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 single-dose oral solution after "Exp". The expiry date refers to the last day of that month.

Do not store above 30°C.

Store invitaD3 in the original carton to protect the contents from light.

If the oral solution within the single-dose oral solution is disccoloured or show signs of any deterioration, you should seek the advice of your pharmacist.

Do not throw away any medicine 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 invitaD3 contains
• Each single-dose oral solution contains colecalciferol (vitamin D3).

• Each single-dose oral solution contains 0.625 mg colecalciferol, equivalent to 25,000 IU vitamin D.

• The other ingredients are tocopherol acetate, polyglyceryl oleate (E475), olive oil, refined, sweet orange peel oil.

What invitaD3 looks like and contents of the pack
invitaD3 is a clear, slightly yellow, oily liquid. It is supplied in transparent PVC/PVDC/PE single-dose oral solution.
invitaD3 is available in packs of 3 PVC/PVDC/PE single-dose oral solutions.
Not all pack sizes may be marketed.
Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
Consilient Health Limited, 0th Floor, Beaune Lane House, Mercer Street Lower, Dublin 2, Ireland.
Manufacturer
SMB Technology S.A. 39, rue du Parc Industriel, 6900 Marche en Famenne, Belgium.

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