160 mm

40 mm

60 mm

240 mm

PACKAGE LEAFLET: INFORMATION FOR THE USER

InVita D3 400 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.
Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 2 weeks.

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. Certain people are at higher risk of vitamin D3 deficiency. This can include people who have limited exposure to sunshine including patients who are hospitalised, obese, have darker skin, difficulty digesting or absorbing vitamin D from food, e.g. inflammatory bowel disease or coeliac disease.

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
- in adults and adolescents over 12 years.

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

Do not take 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), kidneys (nephrocalcinosis) or urine (hypercalciuria)
- if you have kidney stones (renal calculi)
- if you have serious kidney problems
- if you have high levels of vitamin D in your blood (hypervitaminosis D)
- if you have pseudohypoparathyroidism (disturbed parathyroid hormone metabolism)
- if you have sarcoidosis (an immune system disorder which may cause increased level of vitamin D in the body)
- if you are under 12 years of age
- if you are taking thiazide diuretics (to treat high blood pressure)
- if you are taking cardiac glycosides (to treat heart conditions) such as digoxin

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking InVita D3 if you:
- are undergoing treatment with certain medicines used to treat heart disorders (e.g, cardiac glycosides, such as digoxin);
- are taking medicines or food supplements 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
InVita D3 is not suitable for children under 12 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 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 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
InVita D3 should only be used in pregnancy and breast feeding when recommended by a doctor.

If you are pregnant or breast-feeding, think you may be

CONSILIENT CODE : P1588

PLEASE NOTE : PAPER COPIES ARE SUPPLIED AS A VISUAL REFERENCE ONLY. DO NOT MATCH FOR COLOUR

ARTWORK SPECIFICATION		FONTS	COLOURS	DESIGNED BY
Client :	Consilient Health Ltd.	Helvetica Neue	Black	Minty
Project :	Dec 2023			
Item(s) :	InVita D3 400 IU soft capsules			
Size :	160 x 240 mm			
Software :	InDesign CC			

160 mm

40 mm

60 mm

240 mm

pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
See section 3 "How to take InVita D3"

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 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 InVita D3 preferably together with a large meal to help your body absorb the vitamin D.

Use in adults
The recommended dose for:
- **Prevention of vitamin D deficiency:** 800 IU/day (2 capsules)
- **Addition to specific therapy for osteoporosis:** 800 IU/day (2 capsules)

Use in adolescents from 12 years
The recommended dose for:
- **Prevention of deficiency 12-18 years:** 800 IU/day (2 capsules)
- **Treatment of deficiency 12-18 years:** 2000 IU/day (5 capsules) for 6 weeks followed by a maintenance therapy of 400 IU-1200 IU/day (1-3 capsules)

Use in pregnancy and breast-feeding
The recommended dose for:
- **Prevention of deficiency:** 400 IU/day (1 capsule)
- **Treatment of deficiency:** Doses of up to 2000 IU /day (5 capsules) may be required to treat deficiency in some women

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 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 400 IU of colecalciferol (vitamin D3) equivalent to 10 micrograms.
- 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).

What InVita D3 looks like and contents of pack
InVita D3 is a clear, oval-shaped, soft capsule. It contains a slightly yellow oily liquid. Each capsule has "0.4" printed in white ink. Each carton contains 28 capsules packed in blister strips.

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

Manufacturers
Consilient Health (UK) Ltd.,
1 Church Road, Richmond, TW9 2QE, United Kingdom

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

This leaflet was last revised in January 2024.

200024373 P1588

CONSILIENT CODE : P1588

PLEASE NOTE : PAPER COPIES ARE SUPPLIED AS A VISUAL REFERENCE ONLY. DO NOT MATCH FOR COLOUR

ARTWORK SPECIFICATION		FONTS	COLOURS	DESIGNED BY
Client :	Consilient Health Ltd.	Helvetica Neue	Black	Minty
Project :	Dec 2023			
Item(s) :	InVita D3 400 IU soft capsules			
Size :	160 x 240 mm			
Software :	InDesign CC			