

Package leaflet: Information for the user

THORENS 25 000 I.U. /2.5 ml oral solution

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

1. What THORENS is and what it is used for

THORENS oral solution contains the active ingredient 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. Vitamin D₃ deficiency is the predominant cause of rickets (defective mineralization of bones in children) and osteomalacia (inadequate mineralization of bones in adults).

THORENS oral solution is used for initial treatment of clinically relevant vitamin D deficiency in adults.

2. What you need to know before you use THORENS

Do not use THORENS:

- 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) or severe renal impairment;
- if you have high levels of vitamin D₃ in your blood (hypervitaminosis D).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using THORENS if you:

- are undergoing treatment with certain medicines used to treat heart disorders (eg, 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 THORENS;
- 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 THORENS;
- have kidney damage or disease. Your doctor may want to measure the levels of calcium in your blood or urine;
- take a daily dose of vitamin D₃ exceeding 1 000 I.U. over a long period of time, your doctor should monitor the level of calcium in your blood by lab test.

Children and adolescents

The use is not recommended in children and adolescents under 18 years of age.

Other medicines and THORENS

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 (eg, digoxin) or diuretics (eg, bendroflumethiazide). 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 (eg, clotrimazole and ketoconazole, medicines used to treat fungal disease). These medicines may interfere with the way your body processes 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 (eg, orlistat);
 - certain laxatives (such as liquid paraffin).

THORENS with food, drink and alcohol

You should take this medicine preferably together with a large meal to help your body absorb the vitamin D₃. You can also mix the solution with cold or lukewarm food, to help you take this medicine. For detailed information see section 3 “How to use THORENS”.

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 breast-feeding 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.

3. How to use THORENS

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

Shake before use.

You should take THORENS preferably together with a meal.

This medicine has a taste of olive oil. It can be taken on its own from the bottle or to help you take the medicine you can also mix the solution with a small amount of cold or lukewarm food immediately before use. Make sure the entire dose is taken.

Use in adults

The recommended dose is 1 bottle per week during the first month, your doctor will adjust the dose for you.

Paediatric population

THORENS 25 000 I.U. is not recommended in children and adolescents under 18 years of age.

Pregnancy and breast-feeding

THORENS 25 000 I.U. is not recommended.

If you take more THORENS than you should

If you 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 and in urine (hypercalcaemia and hypercalciuria) shown by lab test.

If you forget to take THORENS

If you forget to take a dose of THORENS, 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 (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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store THORENS

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.

Do not store above 30° C.

Keep the bottle in the outer carton in order to protect from light.

Do not freeze or refrigerate.

Do not use this medicine if you notice the solution is cloudy.

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 THORENS contains

- The active substance is colecalciferol (vitamin D₃).
A single-dose bottle of 2.5 ml oral solution contains: 25 000 I.U. colecalciferol (vitamin D₃) equivalent to 0.625 mg
1 ml oral solution contains 10 000 I.U. colecalciferol (vitamin D₃), equivalent to 0.25 mg
- The other ingredient is refined olive oil.

What THORENS looks like and contents of pack

THORENS 25 000 I.U. /2.5 ml oral solution, is a clear and colourless to greenish-yellow oily solution without visible solid particles and/or precipitate. It is supplied in an amber glass bottle sealed with a plastic cap.

Each pack contains 1 or 4 single dose bottles containing 2.5 ml solution.

Not all pack sizes may be marketed.

Marketing authorisation holder

Galen Pharma Ireland Limited
Finnabair Industrial Estate
Dundalk
Co. Louth
A91 P9KD
Ireland

Manufacturer

Abiogen Pharma S.p.A.
Via Meucci, 36 – Pisa (Italy)
info@abiogen.it

This medicinal product is authorised in the Member States of the EEA under the following names:

United Kingdom: THORENS 25 000 I.U. /2.5 ml oral solution

Ireland: THORENS 25 000 I.U. /2.5 ml oral solution

Belgium: THORENS 25 000 UI/2,5 ml solution buvable

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