

Package leaflet: Information for the user

theiCal-D₃

1000 mg / 880 IU chewable tablets

Calcium and Colecalciferol

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

Always take this medicine as described in this leaflet.

- 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 pharmacist. 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 you feel worse.

What is in this leaflet:

1. What TheiCal-D₃ 1000 mg / 880 IU chewable tablets is and what it is used for
2. What you need to know before you take TheiCal-D₃ 1000 mg / 880 IU chewable tablets
3. How to take TheiCal-D₃ 1000 mg / 880 IU chewable tablets
4. Possible side effects
5. How to store TheiCal-D₃ 1000 mg / 880 IU chewable tablets
6. Contents of the pack and other information

1. What TheiCal-D₃ 1000 mg / 880 IU chewable tablets is and what it is used for

TheiCal-D₃ 1000 mg / 880 IU chewable tablets is a calcium-vitamin D₃-supplement.

It is used

- to prevent and treat a lack of calcium and vitamin D in the elderly.
- for vitamin D and calcium supplementation as supportive treatment of osteoporosis (weaker bones and joints).

2. What you need to know before you take TheiCal-D₃ 1000 mg / 880 IU chewable tablets

Do not take TheiCal-D₃

1000 mg / 880 IU chewable tablets

- if you are allergic (hypersensitive) to calcium, vitamin D₃ or any of the other ingredients of TheiCal-D₃ 1000 mg / 880 IU chewable tablets
- if you have high levels of calcium in your blood (hypercalcaemia)
- if you have increased excretion of calcium with your urine (hypercalciuria)
- if you suffer from overactive parathyroid glands (hyperparathyroidism)
- if you suffer from bone marrow cancer (myeloma)
- if you suffer from cancer that has affected your bones (bone metastases)
- if you have a restraint of the limbs (prolonged immobilisation) accompanied with hypercalcaemia and / or hypercalciuria
- if you are taking any other medicines or food supplements containing calcium or vitamin D
- If you are under 18 years of age

You may wish to talk to your pharmacist about the long-term use of this medicine especially:

- if you have or have ever had kidney stones (nephrolithiasis), calcium deposits in your kidneys (nephrocalcinosis) or severe kidney problems
- if you suffer from an excessive supply of vitamin D (hypervitaminosis D)
- if you have sarcoidosis
- if you are taking any medicines, particularly medicines for the heart

Warnings and precautions

Talk to your pharmacist before taking TheiCal-D₃ 1000 mg / 880 IU chewable tablets

- if you are being treated with cardiac glycosides or thiazide diuretics (water tablets) for heart problems they may suggest you need to consult your doctor.
- if you suffer from kidney problems you have to take TheiCal-D₃ 1000 mg / 880 IU chewable tablets with special care.
- take special care when taking TheiCal-D₃ 1000 mg / 880 IU chewable tablets if you suffer from sarcoidosis (an immune system disorder which may affect your liver, lung, skin or lymph nodes). There is a risk that the effect of this medicinal product gets too strong which can result in an overdose of calcium in the body.
- if you are immobile and are suffering from osteoporosis this medicinal product has to be used with special care, as the level of calcium in your blood might increase.

Children and adolescents

TheiCal-D₃ 1000 mg / 880 IU chewable tablets are not intended for use in children and adolescents.

Other medicines and TheiCal-D₃ 1000 mg / 880 IU chewable tablets

Tell your pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

- In the case of simultaneous treatment with digitalis glycosides (cardiac glycosides derived from foxglove), cardiac arrhythmias can occur. Rigorous medical monitoring including an ECG and measurement of the blood calcium level is therefore necessary.
- In the case of simultaneous administration of diuretics of the thiazide drug class (also called water tablets), the blood calcium level should be regularly monitored since thiazides decrease the excretion of calcium in the urine.
- The absorption and thus also the effectiveness of certain antibiotics (called tetracyclines) are decreased by the simultaneous administration of TheiCal-D₃ 1000 mg / 880 IU chewable tablets. These drugs should be taken at least 2 hours before or 4–6 hours after TheiCal-D₃ 1000 mg / 880 IU chewable tablets.
- Furthermore, other medicines such as sodium fluoride (used to strengthen the tooth enamel or to treat osteoporosis) and bisphosphonate (used to treat osteoporosis) drugs are affected by interactions. These products should therefore be taken at least 3 hours before TheiCal-D₃ 1000 mg / 880 IU chewable tablets.
- As long an interval as possible should be left between the administration of cholestyramine (a product to lower raised cholesterol levels) or laxatives such as liquid paraffin and TheiCal-D₃ 1000 mg / 880 IU chewable tablets since otherwise vitamin D is not absorbed properly.
- The simultaneous administration of TheiCal-D₃ 1000 mg / 880 IU chewable tablets and phenytoin (a product for the treatment of epilepsy) or barbiturates (hypnotics) can result in a reduction in the effect of vitamin D.
- The simultaneous administration of TheiCal-D₃ 1000 mg / 880 IU chewable tablets and glucocorticoids (e.g. cortisone) can result in a reduction in the effect of vitamin D and to a decreased calcium level in the blood.
- The additional supplementation of calcium and vitamin D should be given only under medical supervision and will require frequent monitoring of the calcium levels in the blood and urine.
- Calcium can reduce the effect of levothyroxine (used to treat thyroid deficiency). For this reason, levothyroxine should be taken at least four hours before or four hours after TheiCal-D₃ 1000 mg / 880 IU chewable tablets.
- The effect of quinolone antibiotics may be reduced if taken at the same time as calcium. Take quinolone antibiotics two hours before or six hours after taking TheiCal-D₃ 1000 mg / 880 IU chewable tablets.

TheiCal-D₃ 1000 mg / 880 IU chewable tablets with food and drink

You can take TheiCal-D₃ 1000 mg / 880 IU chewable tablets at any time, with or without food.

Please notice that oxalic acid (contained in spinach and rhubarb) and phytic acid (contained in wholegrain cereals) can reduce the amount of calcium you absorb in your bowel. In the 2 hours before or after eating food containing high amounts of oxalic or phytic acid patients should not take medicinal products that contain calcium.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your pharmacist for advice before taking this medicine.

If you are pregnant you may use TheiCal-D₃ 1000 mg / 880 IU chewable tablets in case of a calcium and vitamin D deficiency. The daily dose of half a tablet must not be exceeded. During pregnancy the total daily amount of calcium should not be higher than 1,500 mg and the total daily amount of vitamin D₃ should not be higher than 600 IU (International Units). Long-term overdose of calcium and vitamin D during pregnancy must be avoided since this may lead to high levels of calcium in the blood and may have a negative effect on the unborn child.

TheiCal-D₃ 1000 mg / 880 IU chewable tablets can be used during breast-feeding. As calcium and vitamin D pass into breast-milk check with your pharmacist first if your child receives any other products containing vitamin D.

Driving and using machines

TheiCal-D₃ 1000 mg / 880 IU chewable tablets has no influence on your ability to drive and use machines.

TheiCal-D₃ 1000 mg / 880 IU chewable tablets contain aspartame (E951)

This medicine contains 1 mg aspartame (E951) in each chewable tablet. Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

TheiCal-D₃ 1000 mg / 880 IU chewable tablets contain benzyl alcohol

This medicine contains 0.02 mg benzyl alcohol in each chewable tablet. Benzyl alcohol may cause allergic reactions. Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding or if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").

TheiCal-D₃ 1000 mg / 880 IU chewable tablets contain isomalt (E953) and sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. Sucrose may be harmful to the teeth.

TheiCal-D₃ 1000 mg / 880 IU chewable tablets are essentially 'sodium-free'

This medicine contains less than 1 mmol sodium (23 mg) per chewable tablet, that is to say essentially 'sodium-free'.

TheiCal-D₃ 1000 mg / 880 IU chewable tablets contain sorbitol (E420)

This medicine contains 119.32 mg sorbitol (E420) in each chewable tablet.

3. How to take TheiCal-D₃ 1000 mg / 880 IU chewable tablets

Always take TheiCal-D₃ 1000 mg / 880 IU chewable tablets as described in this leaflet. Check with your pharmacist if you are not sure.

Dosage

Adults and elderly (including with liver disease) take 1 chewable tablet daily (corresponding to 1,000 mg of calcium and 880 IU (International Units) of vitamin D₃).

Pregnant women take only half a chewable tablet daily (corresponding to 500 mg of calcium and 440 IU (International Units) of vitamin D₃). The daily dose of half a tablet must not be exceeded. Do not take if you have severe kidney disease.

Method of administration

The tablet has to be chewed before it is swallowed. It should be taken at any time, with or without food.

Duration of treatment

TheiCal-D₃ 1000 mg / 880 IU chewable tablets should be taken as long-term treatment. Talk to your pharmacist how long you should take TheiCal-D₃ 1000 mg / 880 IU chewable tablets (see also section 2, Take special care with TheiCal-D₃ 1000 mg / 880 IU chewable tablets).

If you take more TheiCal-D₃ 1000 mg / 880 IU chewable tablets than you should

Overdose of TheiCal-D₃ 1000 mg / 880 IU chewable tablets may lead to symptoms such as feeling sick (nausea), vomiting, thirst or excessive thirst, increased urine output, depletion of body fluids or constipation. If an overdose is suspected, contact your doctor or pharmacist immediately.

If you forget to take TheiCal-D₃ 1000 mg / 880 IU chewable tablets

If you forget to take TheiCal-D₃ 1000 mg / 880 IU chewable tablets, take it as soon as you remember. However, do not take a double dose to make up for a forgotten tablet.

If you stop taking TheiCal-D₃ 1000 mg / 880 IU chewable tablets

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

4. Possible side effects

Like all medicines, TheiCal-D₃ 1000 mg / 880 IU chewable tablets can cause side effects, although not everybody gets them. The evaluation of side effects is based on the following frequencies:

Very common:	affects more than 1 user in 10
Common:	affects 1 to 10 users in 100
Uncommon:	affects 1 to 10 users in 1,000
Rare:	affects 1 to 10 users in 10,000
Very rare:	affects less than 1 user in 10,000
Not known:	frequency cannot be estimated from the available data

Stop taking TheiCal-D₃ 1000 mg / 880 IU chewable tablets and contact a healthcare professional immediately

if you experience the following allergic reaction (not known as frequency cannot be estimated from the available data):

- swelling of the face, lips, tongue or throat with sudden difficulty breathing and severe rash.

The other side effects reported are:

Rare side effects:

- feeling sick (nausea), diarrhoea, abdominal pain, constipation, wind, bloating (abdominal distension).
- rash, itching, hives.

Uncommon side effects:

- high levels of calcium in your blood (hypercalcaemia) or urine (hypercalciuria).

Reporting of side effects

If you get any side effects, talk to your pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

United Kingdom

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 TheiCal-D₃ 1000mg / 880 IU chewable tablets

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

Do not use TheiCal-D₃ 1000 mg / 880 IU chewable tablets after the expiry date (EXP) which is stated on the carton and on the tablet container or on the laminated aluminium paper foil. The expiry date (EXP) refers to the last day of that month.

For tablet container: Keep the tablet container tightly closed in order to protect from moisture.

For strips: This medicinal product does not require any special storage conditions.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What TheiCal-D₃ 1000 mg / 880 IU chewable tablets contains

- The active substances are calcium and colecalciferol. Each chewable tablet contains 2,500 mg of calcium carbonate (equivalent to 1,000 mg of calcium) and 8.8 mg of colecalciferol concentrate (powder form) (equivalent to 22 micrograms of colecalciferol = 880 IU of vitamin D₃).
- The other ingredients are isomalt (E953), xylitol, sorbitol (E420), citric acid, anhydrous, sodium dihydrogen citrate, magnesium stearate, carmellose sodium, flavour orange "CPB" (contains benzyl alcohol) and flavour orange "CVT" (which both contain sorbitol (E420)), aspartame (E951), acesulfam potassium, sodium ascorbate, all-rac-alpha-tocopherol, modified (maize) starch, sucrose, triglycerides medium chain and silicon dioxide colloidal.
- This medicinal product contains aspartame (E951), benzyl alcohol (in flavour orange "CPB"), isomalt (E953), sodium, sorbitol (E420) and sucrose. See section 2 "TheiCal-D₃ 1000 mg / 880 IU chewable tablets contain aspartame (E951)/benzyl alcohol/isomalt (E953) and sucrose/are essentially 'sodium-free'/sorbitol (E420)".

What TheiCal-D₃ 1000 mg / 880 IU chewable tablets looks like and contents of the pack

TheiCal-D₃ 1000 mg / 880 IU chewable tablets are round, white tablets with faultless surface and a breakmark. The tablet can be divided into equal halves.

The chewable tablets are available in polypropylene tablet containers with polyethylene stoppers containing a desiccant in the following package sizes: 20, 28, 30, 50, 56, 60, 90, 100 (bundling package 5x20) chewable tablets.

The chewable tablets are available in strips of laminated aluminium paper foil in the following package sizes: 20, 28, 30, 48, 56, 60, 90, 96, 100 (bundling package 5x20) chewable tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Stirling Anglian Pharmaceuticals Limited
Hillington Park Innovation Centre
1 Ainslie Road
Hillington Park
Glasgow
G52 4RU
UK

Manufacturer

HERMES PHARMA GmbH
Georg-Kalb-Straße 5
82049 Pullach i. Isartal
Germany

This leaflet was last revised in July 2021.