Package leaflet: Information for the user

Calcium /Cholecalciferol Theramex 500 mg / 2000 IU,
chewable tablets

calcium/cholecalciferol (vitamin D3)

Read all of this leaflet carefully before you start taking 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.
- 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. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [Invented name] is and what it is used for
2. What you need to know before you take [Invented name]
3. How to take [Invented name]
4. Possible side effects
5. How to store [Invented name]
6. Contents of the pack and other information

1. What [Invented name]are and what they are used for

[Invented name] are a calcium-vitamin D_3-supplement.

It is used
- to treat lack of calcium and vitamin D in adults.

2. What you need to know before you take [Invented name]

Do not take [Invented name]
- if you are allergic to calcium, cholecalciferol (vitamin $D_{3)}$ or any of the other ingredients of this medicine (listed in section 6)
- if you have high levels of calcium in your blood (hypercalcaemia)
- if you have high levels of calcium in 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 restriction in movement of the limbs (prolonged immobilisation) accompanied with hypercalcaemia and / or hypercalciuria
- if you have kidney stones (nephrolithiasis)
- if you have calcium deposits in your kidneys (nephrocalcinosis)
- if you suffer from an excessive supply of vitamin D (hypervitaminosis D)
- if you have severe kidney problems

Warnings and precautions
Talk to your doctor or pharmacist before taking [Invented name]

- if you are on long-term treatment, especially if you also take diuretics (used in the treatment of high blood pressure or oedema) or cardiac glycosides (used to treat heart disorders).
- if you have impaired renal function.
- if you have sarcoidosis (an immune system disorder that may increase vitamin D levels in the body).
- if you have osteoporosis and at the same time are unable to move around.
- if you take other products containing vitamin D. Additional doses of calcium and vitamin D
- should be taken under close medical supervision.

Children and adolescents
[Invented name] are not intended for use in children and adolescents

Other medicines and [Invented name]
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

- Other medicines that may influence or be influenced by [Invented name] are:
  - tiazide diuretics (used in treatment of high blood pressure or oedema)
  - cardiac glycosides (used to treat heart disorders)
  - HIV inhibitors (e.g., raltegravir, dolutegravir, elvitegravir)
- If you also take tetracyclines (a type of antibiotics), you should take these at least two hours before or four to six hours after intake of [Invented name]. Calcium carbonate may interfere with the absorption of tetracycline preparations if taken at the same time.
- Medicines containing bisphosphonates (used to treat osteoporosis) should be taken at least three hours before intake of [Invented name].
- Orlistat (used to treat obesity), cholestyramine (a product to lower raised cholesterol levels) or laxatives such as liquid paraffin may disturb the absorption, and thereby reduce the effect, of fat-soluble vitamins, e.g. vitamin D3.
- Phenytoin (a product for the treatment of epilepsy) or barbiturates (hypnotics) can result in a reduction in the effect of vitamin D.
- Glucocorticoids (e. g. cortisone) can result in a reduction in the effect of vitamin D and a decreased calcium level in the blood.
- 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 [Invented name].
- 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 [Invented name].
- Calcium salts may decrease the absorption of iron, zinc and strontium ranelate. Consequently, iron, zinc or strontium ranelate preparations should be taken at least two hours before or after [Invented name].
- 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.

If you are taking any of the above-mentioned medicines, your doctor will give you further instructions.

[Invented name] with food and drink
You can take [Invented name] at any time, with or without food.

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.

[Invented name] is not recommended during pregnancy in patients without a vitamin D and calcium deficiency. Where there is a vitamin D deficiency the recommended dose is dependent on national guidelines, however, the maximum daily dose should not exceed 2500 mg calcium and 4,000 IU vitamin D per day. 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.

[Invented name] can be used during breast-feeding. As calcium and vitamin D pass into breast-milk check with your doctor first if your child receives any other products containing vitamin D. This should be considered when giving additional vitamin D to the child.

Alternatively, treatment may be switched to other calcium and vitamin D3 containing medicinal products containing vitamin D3 in lower strength.

Driving and using machines
[Invented name] have no influence on your ability to drive and use machines.

[Invented name]contain
- 0.5 mg of aspartame (E951), 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.
- 38.5 mg of sorbitol (E420), 185 mg of isomalt (E953) and 3.85 mg of sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine. May be harmful to the teeth.
- This medicine contains less than 1 mmol sodium (23 mg) per chewable tablet, that is to say essentially 'sodium-free'.
- The medicinal product contains traces of benzyl alcohol. Benzyl alcohol may cause allergic reactions.

3. How to take [Invented name]

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

Recommended dose is 1 chewable tablet daily corresponding to 500 mg of calcium and 2000 IU (International Units) of vitamin D3. The dosage is individually decided for you by your doctor.

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

You should give attention to a sufficient daily intake of calcium by nutrition (i.e. milk products, vegetables, mineral water).

Use in children and adolescents
[Invented name] is **not intended** for use in children and adolescents.

If you take more [Invented name]than you should
Overdose of [Invented name] 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 [Invented name]
If you forget to take [Invented name] 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 Calcium/Cholecalciferol
If you wish to interrupt or prematurely discontinue the treatment, please consult your doctor.

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.

Stop taking [Invented name]and contact a doctor 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:

Uncommon: may affect up to 1 in 100 people
- high levels of calcium in your blood (hypercalcaemia) or urine (hypercalciuria).

Rare: may affect up to 1 in 1,000 people
- feeling sick (nausea), diarrhoea, abdominal pain, constipation, wind, bloating (abdominal distension).
- 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 the national reporting system listed in Appendix V . By reporting side effects you can help providemore information on the safety of this medicine.

5. How to store [Invented name]

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 on the laminated aluminium paper foil. The expiry date refers to the last day of that month.

This medicinal product does not require any special temperature storage conditions. Keep the tablet container tightly closed in order to protect from moisture.

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 [Invented name] contain
- The active substances are calcium and cholecalciferol. Each chewable tablet contains 500 mg calcium (as calcium carbonate) and 50 micrograms cholecalciferol (vitamin D_3, equivalent to 2000 IU) as cholecalciferol-concentrate (powder form).
- The other ingredients are, isomalt (E953), xylitol, sorbitol (E420, citric acid, monosodium citrate, carmellose sodium, magnesium stearate, Flavour Orange “CPB”, Flavour Orange “CVT”, silica, colloidal hydrated, aspartame, acesulfam potassium, sodium ascorbate, all-rac-alpha-tocopherol, modified starch, sucrose and triglycerides, medium chain, silica, colloidal anhydrous, mannitol, benzyl alcohol and propylene glycol.

What [Invented name] look like and contents of the pack
[Invented name]are round, white tablets, diameter 18 mm..

The are available in polypropylene tubes with a polyethylene stopper containing a descant or alternatively laminated aluminium-paper-foil strips. Tear up the strip to open.

Pack sizes
Tubes: 30, 60 (2x30) and 90 (3x30) chewable tablets.

Strips:

30 (5x6), 60 (10x6) and 90 (15x6) chewable tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

[To be completed nationally]
Manufacturer
[To be completed nationally]
This medicinal product is authorised in the Member States of the EEA under the following names:

[To be completed in the final PL]

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