Package leaflet: Information for the patient

Caltrate 500 mg / 1000 IU, chewable tablets

Calcium/Cholecalciferol (Vitamin D_3)

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 or pharmacist 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. 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.

What is in this leaflet

1. What Caltrate 500 mg / 1000 IU, chewable tablets are and what they are used for

Caltrate 500 mg / 1000 IU, chewable tablets are a calcium-vitamin D_3-supplement and belong to the group of calcium carbonates and cholecalciferols. Calcium is an important constituent of Bone and Vitamin D_3 helps the absorption of Calcium by the intestine and its deposition in the bones.
Caltrate 500 mg / 1000 IU, chewable tablets **are 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 (brittle bones).

2. What you need to know before you take Caltrate 500 mg / 1000 IU, chewable tablets

Do not take Caltrate 500 mg / 1000 IU, chewable tablets
- if you are allergic to calcium, 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

Calcium 500mg/1000 IU chewable tablets must not be used in children or adolescents (due to the high content of vitamin D).

Warnings and precautions
Talk to your doctor or pharmacist before taking Caltrate 500 mg / 1000 IU, chewable tablets

- During long-term treatment the levels of calcium in your blood and urine and your kidney function have to be monitored regularly. This is especially important if you have a tendency to develop kidney stones. Depending on your blood levels your doctor might reduce the dosage or discontinue the treatment.
- If you are simultaneously being treated with cardiac glycosides or thiazide diuretics (water tablets) for heart problems the levels of calcium in your blood and urine and your kidney function have to be monitored regularly. Depending on your blood levels your doctor might reduce the dosage or discontinue the treatment.
- If you suffer from kidney problems you have to take Caltrate 500 mg / 1000 IU, chewable tablets with special care. Your calcium levels of the blood and urine have to be checked. If you suffer from severe kidney problems, use other forms of vitamin D than cholecalciferol.
- Take additional supplementation of calcium and vitamin D only under medical supervision and your doctor will require frequent monitoring of the calcium levels in the blood and urine.
- Take special care when taking Caltrate 500 mg / 1000 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. The levels of calcium in the blood and urine have to be monitored.
- 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.
- Co-administration with tetracyclines or quinolones is usually not recommended or must be done with precaution (see “other medicines and Caltrate 500 mg / 1000 IU, chewable tablets”)
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  Children and adolescents:
  Caltrate 500mg/1000 IU chewable tablets must not be used in children or adolescents (due to the high content of vitamin D) (see “Do not take <Caltrate 500 mg / 1000 IU, chewable tablets ”).

Other medicines and Caltrate 500 mg / 1000 IU, chewable tablets
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

- In the case of simultaneous treatment with digitalis glycosides (cardiac glycosides derived from foxglove), changes in the way the heart beats (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 amount of calcium disposed of in the urine.
- The absorption and thus also the effectiveness of certain antibiotics (called tetracyclines) are decreased by the simultaneous administration of Caltrate 500 mg / 1000 IU, chewable tablets. These drugs should be taken at least 2 hours before or 4-6 hours after Caltrate 500 mg / 1000 IU, chewable tablets.
- Furthermore, other medicines such as sodium fluoride (used to strengthen the tooth enamel or to treat osteoporosis), bisphosphonate (used to treat osteoporosis) drugs or iron salts are affected by interactions. These products should therefore be taken at least 2 hours before Caltrate 500 mg / 1000 IU, chewable tablets.
- As long an interval as possible should be left between the administration of Orlistat or ion exchange resins such as cholestyramine or laxatives such as paraffin oil and Caltrate 500 mg / 1000 IU, chewable tablets since otherwise vitamin D is not absorbed properly.
- The simultaneous administration of Caltrate 500 mg / 1000 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 Caltrate 500 mg / 1000 IU, chewable tablets and glucocorticoids (e. g. cortisone) can result in a reduction in the effect of vitamin D and 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 Caltrate 500 mg / 1000 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 Caltrate 500 mg / 1000 IU, chewable tablets.

Caltrate 500 mg / 1000 IU, chewable tablets with food and drink
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, 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.

If you are pregnant you should not use Caltrate 500 mg / 1000 IU, chewable tablets.
Ask your doctor or pharmacist for advice before taking Caltrate 500 mg / 1000 IU, chewable tablets whilst breast-feeding. As calcium and vitamin D pass into breast-milk check with your doctor first if your child is taking any other products containing vitamin D.

Driving and using machines
Caltrate 500 mg / 1000 IU, chewable tablets have no or negligible influence on your ability to drive and use machines.

Caltrate 500 mg / 1000 IU, chewable tablets contain aspartame (E951).
This medicinal product contains 0.5 mg aspartame, in each tablet which is equivalent to 0.3 mg/g.
Aspartame is a source of phenylalanine. It may be harmful for people with phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

Caltrate 500 mg / 1000 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.

This medicinal product contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially sodium free.

Caltrate 500 mg / 1000 IU, chewable tablets contains 58.19 mg sorbitol in each tablet which is equivalent to 33.7 mg/g.

This medicine contains 0.01.mg benzyl alcohol in each tablet which is equivalent to 0.006 mg/ g.
Benzyl alcohol may cause allergic reactions.
Ask you doctor or pharmacist for advice if you are pregnant or breast feeding. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called “metabolic acidosis”).
Ask you doctor or pharmacist for advice 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”).

Caltrate 500 mg / 1000 IU, chewable tablets may be harmful to the teeth.

3. How to take Caltrate 500 mg / 1000 IU, chewable tablets

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:
Adults and elderly take 1 chewable tablet daily (corresponding to 500 mg of calcium and 1000 IU (International Units) of vitamin D_3)

Patients with hepatic impairment:
No dose adjustment is required

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

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

Caltrate 500 mg / 1000 IU, chewable tablets should be taken as long-term treatment. Talk to your doctor about how long you should take this medicine (see also section 2, Warnings and precautions).
Do not exceed the recommended dose

If you take more Caltrate 500 mg / 1000 IU, chewable tablets than you should

If you have taken more Caltrate 500 mg / 1000 IU, chewable tablets than you should **and** experience any of the symptoms of overdose, **stop taking** Caltrate 500 mg / 1000 IU, chewable tablets and **immediately contact your doctor.**

Symptoms of overdose may include: anorexia, excessive thirst, feeling sick (nausea), vomiting, constipation, abdominal pain, muscle weakness, fatigue, mental health problems, increased urine output, bone pain, kidney stones.

In the case of prolonged overdosage, calcium deposits may appear in blood vessels or body tissues and may lead to irreversible renal damage.

In the case of major overdosage, cardiac arrest may occur.

If you forget to take Caltrate 500 mg / 1000 IU, chewable tablets
Do not take a double dose to make up for a forgotten dose.
If you forget to take Caltrate 500 mg / 1000 IU, chewable tablets, take it as soon as you remember.

If you stop taking Caltrate 500 mg / 1000 IU, chewable tablets
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 Caltrate 500 mg / 1000 IU, chewable tablets 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 (affects 1 to 10 users in 1,000) side effects:
- high levels of calcium in your blood (hypercalcaemia).

Rare (affects 1 to 10 users in 10,000) side effects:
- feeling sick (nausea), diarrhoea, abdominal pain, constipation, wind, bloating (abdominal distension), burping, vomiting.
- rash, itching, hives.
- Kidney stones
- high levels of calcium in your urine (hypercalciuria)

Very rare (may affect up to 1 user in 10,000) side effects:
- Milk-alkali syndrome

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any 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; Email: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the saftey of this medicine.

5. How to store Caltrate 500 mg / 1000 IU, chewable tablets

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 after "EXP". The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 Caltrate 500 mg / 1000 IU, chewable tablets contain
- The active substances are calcium and cholecalciferol. Each chewable tablet contains 500 mg calcium (as calcium carbonate) and 25 micrograms cholecalciferol (vitamin D_3, equivalent to 1000 IU) as cholecalciferol concentrate powder form.
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- The other ingredients are isomalt (E953), xylitol, sorbitol (E420), citric acid, anhydrous, sodium dihydrogen citrate, magnesium stearate, carmellose sodium, flavour Orange "CPB", flavour Orange "CVT", silica, colloidal hydrated, aspartame (E951), acesulfam potassium, sodium ascorbate, all-rac-alpha-tocopherol, modified (maize) starch, sucrose, triglycerides medium chain and silicon dioxide colloidal.

What Caltrate 500 mg / 1000 IU, chewable tablets look like and contents of the pack
Caltrate 500 mg /1000 IU, chewable tablets are round, white tablets.

The chewable tablets are available in strips of laminated aluminium paper foil in the following package sizes:
24, 30, 48, 60, 90, 120 chewable tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
GlaxoSmithKline Consumer Healthcare (Ireland) Limited
12 Riverwalk
CityWest Business Campus
Dublin 24,
Ireland.

Manufacturer
Hermes Arzneimittel GmbH
Georg-Kalb-Straße 5-8
DE - 82049 Großhesselohe / Munich

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

Germany- Centrum OsteoMED FOCUS 500 mg/100 I.E. Kautabletten.
Slovakia – Caltrate D_3 500 mg/100 IU zuvacie tablet.
Czech Republic – Caltrate D_3
France – CALTRATE ACTIVE 500 mg/1000 IU, comprimer a sucer ou a croquer.

This leaflet was last revised in

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