

PACKAGE LEAFLET

Package leaflet: Information for the patient

Calciup D₃ 500 mg/440 IU chewable tablets

calcium / colecalciferol

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 after one month.

What is in this leaflet

1. What Calciup D₃ 500 mg/440 IU chewable tablets are and what they are used for
2. What you need to know before you take Calciup D₃ 500 mg/440 IU chewable tablets
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1. What Calciup D₃ 500 mg/440 IU chewable tablets are and what they are used for

Calciup D₃ 500 mg/440 IU chewable tablets contain the active substances calcium and vitamin D₃ and are a calcium-vitamin D₃-supplement.

Calciup D₃ 500 mg/440 IU chewable tablets are used

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

2. What you need to know before you take Calciup D₃ 500 mg/440 IU chewable tablets

Do not take Calciup D₃ 500 mg/440 IU chewable tablets:

- if you are allergic to calcium, 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)
- if you have high levels of calcium in the 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 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
- if you are below 18 years of age.

Warnings and precautions

Talk to your doctor or pharmacist before taking Calciup D₃ 500 mg/440 IU chewable tablets if any of the following applies to you:

- **long-term treatment**
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 dose or discontinue the treatment. If you are taking chewable tablets without medical advice, please always consult its use over the period of one month with your doctor.
- simultaneous treatment with **cardiac glycosides or thiazide diuretics (water tablets)** for heart problems.
In such case the levels of calcium in your blood and urine and your kidney function have to be monitored regularly especially if you are elderly. Depending on your blood levels your doctor might reduce the dose or discontinue the treatment.
- **kidney problems**
If you suffer from kidney problems you have to take Calciup D₃ 500 mg/440 IU chewable tablets with special care, especially if you also receive aluminium-containing products as the citric acid in Calciup D₃ 500 mg/440 IU chewable tablets might increase the uptake of aluminium. Your calcium levels in the blood and urine have to be checked. If you suffer from severe kidney problems, use other forms of vitamin D than cholecalciferol.
- **additional intake of calcium and vitamin D supplementation**
Medical supervision is needed and your doctor will require frequent monitoring of the calcium levels in your blood and urine.
- **sarcoidosis** (an immune system disorder which may affect your liver, lung, skin or lymph nodes).
Take special care when taking Calciup D₃ 500 mg/440 IU chewable tablets if you suffer from sarcoidosis. There is a risk that the effect of this medicine 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.
- **immobilised patients with osteoporosis**
In such case this medicine has to be used with special care, as the level of calcium in your blood might increase. If you are taking Calciup D₃ 500 mg/440 IU chewable tablets in osteoporosis, it is recommended to check your calcium levels in the blood before you start using this product.

Children and adolescents

Calciup D₃ 500 mg/440 IU chewable tablets must not be taken by children and adolescents below 18 years of age, see also “Do not take Calciup D₃ 500 mg/440 IU chewable tablets”.

Other medicines and Calciup D₃ 500 mg/440 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), 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 medicine 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 simultaneous administration of Calciup D₃ 500 mg/440 IU chewable tablets. These medicines should be taken at least 2 hours before or 4-6 hours after Calciup D₃ 500 mg/440 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) medicines are affected by interactions. These products should therefore be taken at least 3 hours before Calciup D₃ 500 mg/440 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 Calciup D₃ 500 mg/440 IU chewable tablets since otherwise vitamin D is not absorbed properly.

Orlistat (a medicine used to treat obesity) may impair the absorption of vitamin D. Take Calciup D₃

500 mg/440 IU chewable tablets at least two hours before or after orlistat.

The simultaneous administration of Calciup D₃ 500 mg/440 IU chewable tablets and **rifampicin** (an antibiotic), **phenytoin** (a product for the treatment of epilepsy) or **barbiturates** (hypnotics) can result in a reduction of the effect of vitamin D.

The simultaneous administration of Calciup D₃ 500 mg/440 IU chewable tablets and **glucocorticoids** (e. g. cortisone) can result in a reduction of the effect of vitamin D and in 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 salts may decrease the absorption of **iron, zinc or strontium**. For this reason, iron, zinc or strontium preparations should be administered at least two hours after oral intake of calcium.

Calcium can reduce the effect of **levothyroxine** (used to treat thyroid deficiency). For this reason, levothyroxine should be taken at least 4 hours before or 4 hours after Calciup D₃ 500 mg/440 IU chewable tablets.

The effect of **quinolone antibiotics** may be reduced if taken at the same time as calcium. Take quinolone antibiotics 2 hours before or 6 hours after taking Calciup D₃ 500 mg/440 IU chewable tablets.

Calcium may reduce the absorption of the **estramustin** (a medicine used in chemotherapy). Take this medicine at least two hours before or after Calciup D₃ 500 mg/440 IU chewable tablets.

Calciup D₃ 500 mg/440 IU chewable tablets with food, drink and alcohol

Please notice that oxalic acid (contained in e.g. spinach and rhubarb) and phytic acid (contained in e.g. 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 you should not take medicines that contain calcium.

Pregnancy and breast-feeding

Pregnancy

If you are pregnant you may use Calciup D₃ 500 mg/440 IU chewable tablets in case of a calcium and vitamin D deficiency.

The daily dose of one chewable 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.

Breast-feeding

Calciup D₃ 500 mg/440 IU chewable tablets 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.

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.

Driving and using machines

Calciup D₃ 500 mg/440 IU chewable tablets has no or negligible influence on the ability to drive and use machines.

Calciup D₃ 500 mg/440 IU chewable tablets contain aspartame, benzyl alcohol, sorbitol, isomalt, sucrose and sodium

This medicine contains 0.5 mg aspartame 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.

This medicine contains 0.01 mg benzyl alcohol in each chewable tablet. Benzyl alcohol may cause allergic reactions.

This medicine contains up to 59.66 mg sorbitol in each chewable tablet.

It also contains isomalt and 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'.

3. How to take Calciup D₃ 500 mg/440 IU chewable tablets

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Do not take Calciup D₃ 500 mg/440 IU chewable tablets over the period of one month without medical advice. If you want to use this product over this period, please consult your doctor (see also section 2 - Warnings and precautions).

The recommended dose is:

Adults and elderly

Adults and elderly take one chewable tablet twice daily (corresponding to a total daily dose of 1,000 mg of calcium and 880 IU (International Units) of vitamin D₃).

Pregnant women

Pregnant women take one chewable tablet only once daily (corresponding to 500 mg of calcium and 440 IU (International Units) of vitamin D₃). The daily dose of one chewable tablet must not be exceeded.

Use in children and adolescents

Calciup D₃ 500 mg/440 IU chewable tablets must not be taken by children and adolescents below 18 years of age, see also "Do not take Calciup D₃ 500 mg/440 IU chewable tablets".

Method of administration

Oral use.

The chewable tablet has to be chewed before it is swallowed.

You can take Calciup D₃ 500 mg/440 IU chewable tablets at any time, with or without food.

Duration of treatment

Calciup D₃ 500 mg/440 IU chewable tablets should be taken as long-term treatment. Talk to your doctor or pharmacist how long you should take this medicine (see also Warnings and precautions).

If you take more Calciup D₃ 500 mg/440 IU chewable tablets than you should

Contact your doctor or pharmacist immediately if you suspect an overdose and have the package and any remaining chewable tablets available.

Overdose of Calciup D₃ 500 mg/440 IU chewable tablets may lead to symptoms such as feeling sick (nausea), vomiting, thirst or excessive thirst, increased urine output, dehydration or constipation, frequent urination, enduring headache, enduring loss of appetite, unusual fatigue or weakness together with elevated calcium levels in your blood and kidney problems (milk-alkali syndrome, see also Possible side effects).

If you forget to take Calciup D₃ 500 mg/440 IU chewable tablets

If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. In that case just take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Calciup D₃ 500 mg/440 IU chewable tablets

Please consult your doctor if you wish to interrupt or prematurely discontinue treatment.

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 Calciup D₃ 500 mg/440 IU chewable tablets and contact your doctor immediately if you experience any of the following serious side effects:

Very rare (may affect up to 1 in 10,000 people):

- frequent urination, enduring headache, enduring loss of appetite, nausea or vomiting, unusual fatigue or weakness together with elevated calcium levels in your blood and kidney problems which usually occurs after excessive calcium intake (milk-alkali syndrome).

Rare (may affect up to 1 in 1,000 people):

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

Other side effects reported are:

Uncommon (may affect up to 1 in 100 people):

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

Rare (may affect up to 1 in 1,000 people):

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

If you have renal impairment, you are at increased risk for high level of phosphate in the blood, increased calcium levels in the kidneys and kidney stones.

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: HPRA Pharmacovigilance; website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Calciup D₃ 500 mg/440 IU chewable tablets

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

Do not use this medicine after the expiry date (EXP) which is stated on the carton and on the tablet container or on the laminated aluminium paper foil after “EXP”. The expiry date refers to the last day of that month.

This medicinal product 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 protect the environment.

6. Contents of the pack and other information

What Calciup D₃ 500 mg/440 IU chewable tablets contain

- The active substances are calcium and colecalciferol (vitamin D₃). Each chewable tablet contains 500 mg of calcium (as carbonate) and 440 IU of colecalciferol (vitamin D₃) (equivalent to 11 micrograms of colecalciferol).
- The other ingredients are isomalt (E953), xylitol, sorbitol (E420), citric acid, anhydrous, sodium dihydrogen citrate, magnesium stearate, carmellose sodium, flavour orange “CPB” 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 silica, colloidal anhydrous. Flavour orange “CPB” also contains benzyl alcohol as part of the natural/nature identical mandarine oil.

What Calciup D₃ 500 mg/440 IU chewable tablets look like and contents of the pack

Round, white tablets with faultless surface.

The chewable tablets are packed in strips of laminated aluminium paper foil and inserted in a carton.

Pack sizes:

10, 20, 30, 48, 50, 90, 100 and 120 chewable tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers

Hermes Pharma GmbH, Hans-Urmiller-Ring 52, 82515 Wolfratshausen, Germany.

Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.

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

IE Calciup D₃ 500 mg/440 IU chewable tablets

NL Calcium/Vitamine D₃ Sandoz 500 mg/440 IE, kauwtabletten

This leaflet was last revised in 06/2021.