Package leaflet: Information for the user

Kalcipos-D 500 mg/400 IU chewable tablet
calcium/cholecalciferol (vitamin D_3)

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.
- 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. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Kalcipos-D is and what it is used for

Kalcipos-D is used to prevent and treat calcium and vitamin D_3 deficiency in elderly, and as an adjunct in the management of osteoporosis, when a risk of deficiency of calcium or vitamin D_3 is suspected.

Kalcipos-D contains calcium and vitamin D_3 which both are important components for the formation of bone. Vitamin D_3 regulates the uptake and metabolism of calcium as well as the incorporation of calcium in bone tissue.

2. What you need to know before you take Kalcipos-D

Do not take Kalcipos-D
- if you are allergic to calcium, cholecalciferol or any of the other ingredients of this medicine (listed in section 6).
- if you have an increased level of calcium in the blood (hypercalcaemia) or urine (hypercalciuria) or you have a condition that can cause an increased level of calcium in your blood or urine (e.g. overactive parathyroid glands, a disease of the bone marrow (myeloma), malignant bone tumours (bone metastases)).
- if you have an increased level of vitamin D in the blood (hypervitaminosis D).
- if you have kidney stones (nephrolithiasis) or calcium deposits in your kidneys (nephrocalcinosis).
- if you are suffering from kidney failure.

Warnings and precautions
Talk to your doctor or pharmacist before taking Kalcipos-D:
- if you suffer from sarcoidosis (a special type of connective tissue disease that affects the lungs, skin and joints). Consult your doctor before you start treatment with Kalcipos-D.

- when concomitant use of other medicines containing vitamin D or calcium.
- if you suffer from renal insufficiency. Then you should consult a doctor before starting with the treatment with Kalcipos-D.
- if you suddenly are confined to bed or sitting for a longer time.

Children and adolescents
Kalcipos-D chewable tablets are not intended for use in children.

Other medicines and Kalcipos-D
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines

The effect of the treatment can be affected if this drug is taken simultaneously with certain other medicines against:
- high blood pressure (thiazide diuretics)
- heart problems (cardiac glycosides such as digoxin)
- high cholesterol (cholestyramine)
- constipation (laxatives, such as liquid paraffin)
- epilepsy (phenytoin or barbiturates)
- inflammatory conditions/suppression of immunity (corticosteroids)

Please make sure your doctor knows if you are taking any of the medicines listed above. Your dosage may need to be adjusted.

If you simultaneously use certain medicines for;
- infection (tetracycline or quinolone antibiotics), you should take these two hours before or six hours after oral intake of Kalcipos-D.
- thyroid deficiency (levothyroxine), intake should be separated by at least four hours.
- cancer treatment (estramustine), Kalcipos-D and estramustine should be takenat least two hours apart.
- osteoporosis (bisphosphonates), you should take these medicines at least three hours before Kalcipos-D.
- caries (sodium fluoride), you should take these medicines at least three hours before Kalcipos-D.

Calcium salts may decrease the uptake of iron, zinc and strontium ranelate. Therefore iron, zinc or strontium ranelate preparations should be taken at least two hours before or after Kalcipos-D.

Orlistat (used to treat obesity) may disturb the absorption of fat-soluble vitamins, e.g. vitamin D_3.

Kalcipos-D with food and drink
The effect can be influenced by food containing oxalic acid (found in spinach and rhubarb) and phytic acid (found in whole cereals). You should wait at least two hours before you take Kalcipos-D if you have eaten food with high content of oxalic acid or phytic acid.

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 doctor or pharmacist for advice before taking this medicine.

If you do not have a confirmed calcium and vitamin D deficiency during pregnancy, your daily intake should not exceed 1500 mg calcium and 600 IU vitamin D_3.

If you have a confirmed calcium and vitamin D deficiency during pregnancy, your daily intake must not exceed 2000 mg calcium and 4000 IU vitamin D_3 as overdoses may harm the unborn child.

Calcium and vitamin D_3 pass over into breast milk. This should be considered when giving additional vitamin D to the child. To avoid an overdose for your infant, your doctor will discuss with you

whether you should breast-feed, discontinue breast-feeding or adjust your therapy considering the benefit to you of your therapy and the benefit to your baby of breast-feeding.

Driving and using machines
Kalcipos-D has no known effects on ability to drive or use machines.

Kalcipos-D contains glucose and sucrose
One tablet contains 200 mg glucose and 0.9 mg 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.

May be harmful to teeth.

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

3. How to take Kalcipos-D

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

The recommended dose: 1 chewable tablet 1-2 times daily. The tablet may be chewed or slowly melt in the mouth.

If you take more Kalcipos-D than you should
If you have taken more of this medicine than directed, or if a child accidentally has taken this medicine, please contact your doctor or emergency unit for judgement of the risk and advice.

Symptoms of overdose may include loss of appetite, thirst, nausea, vomiting, constipation, abdominal pain, muscle weakness, fatigue, mental disturbances, excessive thirst, increased urge to urinate, bone pain, calcium deposits in the kidneys, kidney stones, and in severe cases irregular heart rhythm.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

You should stop taking Kalcipos-D and see your doctor immediately if you experience symptoms of angioedema, such as
- swollen face, tongue or lips
- difficulties to swallow
- hives and difficulties to breath.
Frequency not known (cannot be estimated from the available data).

Uncommon (may affect up to 1 in 100 people): hypercalcaemia (increased levels of serum calcium) and/or hypercalciuria (increased levels of urine calcium).

Rare (may affect up to 1 in 1,000 people): constipation, flatulence, nausea, abdominal pain, diarrhoea, pruritus, rash and urticaria.

Very rare (may affect up to 1 in 10,000 people): Milk-alkali syndrome, usually only seen when excessive amounts of calcium have been ingested (symptoms are frequent urge to urinate, headache, loss of appetite, nausea or vomiting, unusual tiredness or weakness, along with elevated levels of calcium in the blood and kidney impairment).

Not known (frequency cannot be estimated from the available data): Hypersensitivity reactions such as swelling of the throat (laryngeal oedema).

Patients with renal impairment are at potential risk of high levels of phosphate in blood, kidney stones formation and calcification of the kidneys.

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- *to be completed nationally*>. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Kalcipos-D

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

Store below 25°C. Store in the original package in order to protect from light. Keep the container tightly closed in order to protect from moisture.

Do not use this medicine after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

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 Kalcipos-D contains
- The active substances are calcium carbonate 1300 mg corresponding to calcium 500 mg and cholecalciferol 10 microgram corresponding to 400 IU vitamin D_3.
- The other ingredients are liquid glucose, magnesium stearate, sodium citrate, xylitol (sweetener), all-*rac*-alpha-tocopherol, sucrose, acacia, sodium laurilsulphate, sodium ascorbate, medium chain triglycerides, starch sodium octenyl succinate (E 1450), silicon dioxide. See also section 2 ‘Kalcipos-D contains glucose and sucrose’ and ‘sodium content’.

What Kalcipos-D looks like and contents of the pack
Kalcipos-D is a chewable tablet.
The tablet is round, white, diameter 17 mm, engraved R 137.

90, 135 and 180 tablets in plastic bottles. Package with accessibility cap is especially adjusted for people with reduced function in the hands. Not all pack sizes may be marketed.

Marketing Authorisation Holder
[To be completed nationally]

Manufacturer
[To be completed nationally]

This leaflet was last revised in February 2026