

calcium/cholecalciferol (vitamin D₃)

Patient Information Leaflet

Read all of this leaflet carefully before you start taking this medicine.

- * 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- * If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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

Kalcipos-D forte is used to prevent and treat calcium and vitamin D₃ deficiency in the elderly, and as an additional treatment in the management of osteoporosis, when a risk of deficiency of calcium and vitamin D₃ is suspected.

Kalcipos-D forte contains calcium and vitamin D₃ which both are important components for the formation of bone. Vitamin D₃ regulates the uptake and metabolism of calcium as well as the incorporation of calcium in bone tissue.

Ask your doctor, pharmacist or other health personal if you have further questions and always follow their instructions.

2 Before you take Kalcipos-D forte

Do not take Kalcipos-D forte

- * if you are allergic (hypersensitive) to the active substances or any of the other ingredients.
- * if you have hypercalcaemia (increased levels of calcium in the blood) or hypercalciuria (increased levels in the urine).
- * if you have hypervitaminosis D (increased levels of vitamin D in the blood).
- * if you have kidney stones
- * if you have kidney failure

Take special care with Kalcipos-D forte

- * if you suffer from sarcoidosis (a special type of connective tissue disease that affects the lungs, skin and joints).
- * if you are taking other drugs containing vitamin D or calcium.
- * if you have poor kidney function or high tendency of renal stone formation.
- * if you are immobilized with osteoporosis.

Consult your doctor before taking Kalcipos-D forte if any of the above points apply to you.

Taking other medicines

Tell your doctor or pharmacy staff if you take or recently have taken other drugs, even non prescription drugs.

The effect of the treatment can be affected if this drug is taken simultaneously with certain other drugs against:

- * high blood pressure (thiazide diuretic)
- * 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 a certain drug for;

- * osteoporosis (bisphosphonates)

you should take this at least one hour before you take Kalcipos-D forte.

If you simultaneously use certain drugs for;

- * infection (quinolones)

you should take these two hours before or six hours after taking Kalcipos-D forte.

If you simultaneously use certain drugs for;

- * infection (tetracyclines)

you should take these two hours before or four to six hours after taking Kalcipos-D forte.

If you simultaneously take certain drugs for;

- * dental caries (sodium fluoride)

- * anaemia (iron)

you should take these drugs at least three hours before taking Kalcipos-D forte.

If you simultaneously use a certain drug for;

- * hypothyroidism (levothyroxine)

you should separate the intake with Kalcipos-D forte by at least four hours.

Taking Kalcipos-D forte with food and drink

The calcium absorption may be inhibited 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 forte if you have eaten food with high content of oxalic acid or phytic acid.

Pregnancy and breast-feeding

During pregnancy the daily intake should not exceed 1500 mg calcium and 600 IU vitamin D.

Kalcipos-D forte is therefore not recommended during pregnancy. However, Kalcipos-D forte can be used during pregnancy, in case of a calcium and vitamin D deficiency.

Kalcipos-D forte can be used during breast-feeding. Calcium and vitamin D₃ pass over into breast milk. This should be considered when giving additional vitamin D to the child.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Kalcipos-D forte has no known effects on ability to drive or use machines.

Important information about some of the ingredients of Kalcipos-D forte

One tablet Kalcipos-D forte chewable tablet contains 200 mg glucose and 1.8 mg sucrose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

Kalcipos-D forte contains glucose that can be harmful to your teeth and it is therefore important to maintain good oral hygiene.

3 How to take Kalcipos-D forte

The dosage is individually decided for you by your doctor.

Usual dose: 1 tablet daily.

The chewable tablet should be chewed or slowly melted in the mouth, never swallowed whole.

Kalcipos® -D forte 500 mg/800 IU chewable tablets

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calcium/cholecalciferol (vitamin D₃)

Patient Information Leaflet (continued)

The amount of calcium in Kalcipos-D forte is lower than the usually recommended daily intake. Kalcipos-D forte is therefore meant for patients with need for additional vitamin D, but with a dietary intake of 500-1000 mg of calcium per day. The dietary intake of calcium should be estimated by the prescriber.

Kalcipos-D forte are not intended for use in children and adolescents.

If you take more Kalcipos-D forte than you should

If you may have taken more Kalcipos-D forte than you should, talk to your doctor or pharmacist immediately.

Some symptoms of overdose of Kalcipos-D forte are loss of appetite, thirst, abnormal increased urine secretion, nausea, vomiting and constipation.

If you forget to take Kalcipos-D forte

Do not take a double dose to make up for a forgotten tablet.

4 Possible side effects

Like all medicines, Kalcipos-D forte can cause side effects, although not everybody gets them.

You should stop taking Kalcipos-D forte and see your doctor immediately if you experience symptoms of serious allergic reactions, such as

- * swollen face, lips, tongue or throat
- * difficult to swallow
- * hives and difficulty breathing

Uncommon (affects 1 to 10 users in 1,000): hypercalcaemia (increased levels of serum calcium) and/or hypercalciuria (increased levels of urine calcium).

Rare (affects 1 to 10 users in 10,000): constipation, flatulence, nausea, abdominal pain, diarrhoea, pruritus, rash and urticaria.

Not known (frequency cannot be estimated from the available data): Serious allergic reactions.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible 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; e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Kalcipos-D forte

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 label and the carton. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light. Keep the container tightly closed in order to protect from moisture. The shelf life after first opening the container is 6 months.

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 Further information

What Kalcipos-D forte contains

- * The active substances are calcium carbonate corresponding to calcium 500 mg and cholecalciferol 20 microgram corresponding to 800 IU Vitamin D₃.
- * The other ingredients are liquid spray dried glucose, magnesium stearate, sodium citrate, xylitol, all-*rac*-alpha-tocopherol, acacia, sodium laurilsulfate, sucrose, medium chain triglycerides, starch sodium octenyl succinate (E 1450), silicon dioxide, sodium ascorbate.

What Kalcipos-D forte looks like and contents of the pack

Kalcipos-D forte is a chewable tablet, white to off white, round and engraved R152 on one side.

Pack size of 30 chewable tablets in plastic bottles.

The Parallel Product Authorisation Holder is:

LTT Pharma Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK.

Repackaged by:

Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE, UK.

The manufacturer is:

Recipharm Stockholm AB, Lagervägen 7, SE-136 50 Jordbro, Sweden

Kalcipos-D is a registered trademark of MEDA AB.

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Blind or partially sighted?

Is this leaflet hard to see or read?

Phone LTT Pharma Limited,

Tel: +44 (0)1527 505414 for help.

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

Sweden, Hungary: Recicalc-D forte 500 mg/800 IU

Germany: Calcipot

Bulgaria, Cyprus, Estonia, Finland, Greece, Ireland, Italy, Latvia,

Lithuania, Luxemburg, Iceland: Kalcipos-D forte 500 mg/800 IU

Portugal: Recifor

Malta, Spain, Poland, United Kingdom: Kalcipos-D 500 mg/800 IU

Norway: Kalcipos-Vitamin D 500 mg/800 IU

Slovakia: Kombi-Kalz

Austria: Maxi-Kalz Vit. D 500 mg/800 IU

Belgium: Maxical

Denmark: Kalcipos-D

The Netherland: Kalcipos-D 500 mg/800 IE kauwtablet

Czech Republic: Calcium/Vitamin D3 Meda 500 mg/800 IU žvýkáci tablety

France: Calcium Vitamine D3 MEDA PHARMA 500 mg/800 UI

Romania: Kalcipos-D forte 500 mg/800 IU comprimate masticabile

Slovenia: Kalcipos 500 mg/800 i.e. žvečljive tablete