

Package leaflet: Information for the user

Kalcipos®-D forte 500 mg/800 IU
chewable tablets
calcium/cholecalciferol (Vitamin D₃)

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:

- What Kalcipos-D forte is and what it is used for
- What you need to know before you take Kalcipos-D forte
- How to take Kalcipos-D forte
- Possible side effects
- How to store Kalcipos-D forte
- Contents of the pack and other information

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

Do not take Kalcipos-D forte

- if you have hypercalcaemia (increased levels of calcium in the blood) or hypercalciuria (increased levels in the urine).
- if you have kidney stones
- if you have calcium depositions in the kidneys

- if you have hypervitaminosis D (increased levels of vitamin D in the blood).
- if you have severely impaired kidney function/kidney failure
- if you are allergic to calcium, cholecalciferol (Vitamin D) or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Kalcipos-D forte if you

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

Children and adolescents

Do not give this medicine to children and adolescents as there is no relevant indication of use in this age group.

Other medicines and Kalcipos-D forte

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, even non-prescription medicines.

The effect of the treatment can be affected if this medicine is taken simultaneously with certain other medicines 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.

How to take simultaneously used medicines

If you simultaneously use certain medicines for;

- osteoporosis (bisphosphonates) you should take this at least one hour before you take Kalcipos-D forte.
- infection (quinolones) you should take these two hours before or six hours after taking Kalcipos-D forte.
- infection (tetracyclines) you should take these two hours before or four to six hours after taking Kalcipos-D forte.
- dental caries (sodium fluoride) you should take these medicines at least three hours before taking Kalcipos-D forte.
- hypothyroidism (levothyroxine) you should separate the intake with Kalcipos-D forte by at least four hours.

If you simultaneously use a certain medicine that contains iron, zinc or strontium ranelate (for treatment of severe osteoporosis) you should separate the intake with Kalcipos-D forte by at least two hours.

Treatment with orlistat (medicine against obesity) may possibly impair the absorption of fat-soluble vitamins (e.g. vitamin D₃).

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 of supplemental calcium and vitamin D should not exceed 1500mg calcium and 600 IU vitamin D in healthy women. Kalcipos-D forte should therefore not be used for the prevention of a calcium and vitamin D deficiency during pregnancy, but can be used in pregnant women who are at high risk of developing or already suffer from 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.

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

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

Kalcipos-D forte contains glucose and sucrose

One tablet Kalcipos-D forte chewable tablet contains 200mg glucose and 1.8mg 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

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. The recommended dose is 1 tablet daily.

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

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 500-1000mg of calcium per day. The dietary intake of calcium should be estimated by the prescriber.

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 (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.

Not known (frequency cannot be estimated from the available data):

Serious allergic reactions.

Special populations

Patients with reduced kidney function are at potential risk of developing abnormally high phosphate levels in the blood (this will generally have no symptoms), kidney stones and calcium depositions in the kidneys (symptoms may include blood in the urine, back pain or abdominal pain).

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 out of the sight and reach of children.

Do not use Kalcipos-D forte after the expiry date (Exp) which is stated on the label. The expiry date refers to the last day of that month.

Shelf-life after first opening container: 6 months

Store in the original package in order to protect from light.

Keep the container tightly closed in order to protect from moisture.

If your doctor decides to stop the treatment, return any leftover medicine to the pharmacist. Only keep it if your doctor tells you to.

If your medicine appears to be discoloured or shows any other signs of deterioration, please return to your pharmacist who will advise you further.

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. Contents of the pack and other information

What Kalcipos-D forte contains

Each chewable tablet contains calcium carbonate equivalent to 500mg calcium and cholecalciferol 20 microgram corresponding to 800 IU Vitamin D₃.

The other ingredients are: liquid spray dried glucose, magnesium stearate, all-*rac*-alpha-tocopherol, sodium citrate, xylitol, acacia, sodium laurilsulfate, medium chain triglycerides, sucrose, starch sodium octenyl succinate (E1450), silicon dioxide and sodium ascorbate.

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

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

Kalcipos-D forte comes in a plastic container with a screw cap containing 30 tablets.

Manufacturer

Manufactured by: Recipharm Stockholm AB, Lagervägen 7, SE-136 50 Jordbro, Sweden.

Procured from within the EU and repackaged by: Doncaster Pharmaceuticals Group Ltd., Kirk Sandall, Doncaster, DN3 1QR, UK.

PPA holder: Imbat Ltd., Unit L2, North Ring Business Park, Santry, Dublin 9.

Distributed by: Eurodrug Ltd., Unit L2, North Ring Business Park, Santry, Dublin 9.

PPA1151/162/001

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Kalcipos®-D is a registered trademark of MEDA AB.

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

Sweden, Hungary	Recicalc-D forte 500mg/800IU
Germany	Calcipot
Bulgaria, Cyprus, Estonia, Finland, Greece, Ireland, Italy, Latvia, Lithuania, Luxemburg, Iceland	Kalcipos-D forte 500mg/800 IU
Malta, Poland, United Kingdom	Kalcipos-D 500mg/800 IU
Norway	Kalcipos-Vitamin D 500mg/800 IU
Slovakia	Kombi-Kalz
Austria	Calciduran Vit. D3 500 mg/800 I.E. Kautabletten
Belgium	Maxical
Denmark	Kalcipos-D
The Netherlands	Kalcipos-D 500mg/800 IE kauwtablet
Czech Republic	Calcium/Vitamin D3 Meda 500mg/800 IU žvýkáci tablety
France	Calcium Vitamine D3 MEDA PHARMA 500mg/800 UI
Romania	Kalcipos-D forte 500mg/800 IU comprimate masticabile
Slovenia	Kalcipos 500mg/800 i.e. žvečljive tablete

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(Regulatory)