Recikalc-D forte 500 mg/800 IU film-coated tablets
Calcium/cholecalfiferol (Vitamin D3)

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1. What Recikalc-D forte is and what it is used for

Recikalc-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.

Recikalc-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 Recikalc-D forte

Do not take Recikalc-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 Recikalc-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 Recikalc-D forte
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 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 Recikalc-D forte.

- infection (quinolones) you should take these two hours before or six hours after taking Recikalc-D forte.

- infection (tetracyclines) you should take these two hours before or four to six hours after taking Recikalc-D forte.

- dental caries (sodium fluoride) you should take these medicines at least three hours before taking Recikalc-D forte.

- hypothyroidism (levothyroxine) you should separate the intake with Recikalc-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 Recikalc-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 D$_3$).

**Recikalc-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 Recikalc-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 1500 mg calcium and 600 IU vitamin D in healthy women. Recikalc-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.

Recikalc-D forte can be used during breast-feeding. Calcium and vitamin D$_3$ 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**
Recikalc-D forte has no known effects on ability to drive or use machines.

**Recikalc-D forte contains sucrose**
One Recikalc-D forte film-coated tablet contains 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.

**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 Recikalc-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 tablets can be swallowed with water whole, divided or crushed.

The amount of calcium in Recikalc-D forte is lower than the usually recommended daily intake. Recikalc-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.

**If you take more Recikalc-D forte than you should**
If you have taken more of this medicine than you should, talk to your doctor or pharmacist immediately.
Some symptoms of overdose of Recikalc-D forte are loss of appetite, thirst, abnormal increased urine secretion, nausea, vomiting and constipation.

**If you forget to take Recikalc-D forte**
Do not take a double dose to make up for a forgotten tablet.

4. **Possible side effects**
Like all medicines, Recikalc-D forte can cause side effects, although not everybody gets them.

You should stop taking Recikalc-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 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 listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. **How to store Recikalc-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. The expiry date refers to the last day of that month.
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 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 Recikalc-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 maltodextrin, sucrose, all-\textit{rac}-alpha-tocopherol, croscarmellose sodium, silica colloidal anhydrous, magnesium stearate, hypromellose, macrogol and paraffin. Medium chain triglycerides, starch sodium octenyl succinate (E 1450), silicon dioxide, sodium ascorbate. See also section 2 ‘Recikalc-D forte contains sucrose’ and ‘Sodium content’.

What Recikalc-D forte looks like and contents of the pack
Recikalc-D forte is a film-coated tablet, white, oval and engraved R150 on one side.
Pack sizes of 20, 30, 40, 50, 60, 90, 100 and 180 tablets in plastic bottles.
Not all pack sizes may be marketed.

Marketing Authorisation Holder
[To be completed nationally]

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

[or]

Rottapharm Ltd
Damastown Industrial Park
Mulhuddart
Dublin 15
Ireland

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

Austria: Calciduran Vit D3
Denmark, United Kingdom: Kalcipos-D
Finland, Ireland: Kalcipos-D forte
Italy: Calciduran
Netherlands: Calcium/Vitamine D3 Mylan 500 mg/800 IE
Norway: Kalcipos-Vitamin D
Portugal: Recifor
Slovakia: Kombi-Kalz
Sweden: Recikalc-D forte
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