

## **Package leaflet: Information for the patient**

### **Calciup D<sub>3</sub> Forte 1000 mg/880 IU Chewable tablets**

calcium/cholecalciferol (vitamin D<sub>3</sub>)

**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 has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If 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.

#### **What is in this leaflet**

1. What Calciup D<sub>3</sub> Forte 1000 mg/880 IU Chewable tablets are and what they are used for
2. What you need to know before you take Calciup D<sub>3</sub> Forte 1000 mg/880 IU Chewable tablets
3. How to take Calciup D<sub>3</sub> Forte 1000 mg/880 IU Chewable tablets
4. Possible side effects
5. How to store Calciup D<sub>3</sub> Forte 1000 mg/880 IU Chewable tablets
6. Contents of the pack and other information

#### **1. What Calciup D<sub>3</sub> Forte 1000 mg/880 IU Chewable tablets are and what they are used for**

Calciup D<sub>3</sub> Forte 1000 mg/880 IU Chewable tablets contain the active substances calcium and vitamin D<sub>3</sub> and is a calcium-vitamin D<sub>3</sub>-supplement.

#### **Calciup D<sub>3</sub> Forte 1000 mg/880 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 D<sub>3</sub> Forte 1000 mg/880 IU Chewable tablets**

##### **Do not take Calciup D<sub>3</sub> Forte 1000 mg/880 IU Chewable tablets**

- if you are allergic to calcium, vitamin D<sub>3</sub> 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 D<sub>3</sub> Forte 1000 mg/880 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.

- 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 D<sub>3</sub> Forte 1000 mg/880 IU Chewable tablets with special care, especially if you also receive aluminium-containing products as the citric acid in Calciup D<sub>3</sub> Forte 1000 mg/880 IU Chewable tablets might increase the uptake of aluminium. Your calcium levels of 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 D<sub>3</sub> Forte 1000 mg/880 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.

### Children and adolescents

Calciup D<sub>3</sub> Forte 1000 mg/880 IU Chewable tablets must not be taken by children and adolescents below 18 years of age, see “Do not take Calciup D<sub>3</sub> Forte 1000 mg/880 IU Chewable tablets”.

### Other medicines and Calciup D<sub>3</sub> Forte 1000 mg/880 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 the simultaneous administration of Calciup D<sub>3</sub> Forte 1000 mg/880 IU Chewable tablets. These medicines should be taken at least 2 hours before or 4-6 hours after Calciup D<sub>3</sub> Forte 1000 mg/880 IU Chewable tablets.
- Furthermore, other medicines such as **sodium fluoride** (used to strengthen the tooth enamel or to treat osteoporosis), **quinolone antibiotics** and **bisphosphonate** (used to treat osteoporosis) medicines are affected by interactions. These products should therefore be taken at least 3 hours before Calciup D<sub>3</sub> Forte 1000 mg/880 IU Chewable tablets.
- As long an interval as possible should be left between the administration of **cholestyramine** (a product to lower raised cholesterol levels), **orlistat** (a medicine used to treat obesity) or **laxatives** such as liquid paraffin and Calciup D<sub>3</sub> Forte 1000 mg/880 IU Chewable tablets since otherwise vitamin D is not absorbed properly.
- The simultaneous administration of Calciup D<sub>3</sub> Forte 1000 mg/880 IU Chewable tablets and **rifampicin** (an antibiotic), **phenytoin** (a product for the treatment of epilepsy) or **barbiturates** (hypnotics) can result in a reduction in the effect of vitamin D.
- The simultaneous administration of Calciup D<sub>3</sub> Forte 1000 mg/880 IU Chewable tablets and **glucocorticoids** (e. g. cortisone) can result in a reduction in the effect of vitamin D and to 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 may reduce the absorption of **iron, zinc or strontium ranelate**. Take these medicines at least two hours before or after Calciup D<sub>3</sub> Forte 1000 mg/880 IU Chewable tablets.
- Calcium may reduce the absorption of the **estramustin** (a medicine used in chemotherapy) and **thyroid hormones** (used to treat thyroid deficiency). Take this medicine at least two hours after Calciup D<sub>3</sub> Forte 1000 mg/880 IU Chewable tablets.

### **Calciup D<sub>3</sub> Forte 1000 mg/880 IU Chewable tablets with food, drink and alcohol**

Please notice that oxalic acid (e.g. contained in spinach and rhubarb) and phytic acid (e.g. contained in 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 D<sub>3</sub> Forte 1000 mg/880 IU Chewable tablets in case of a calcium and vitamin D deficiency.

The daily dose of half a 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 D<sub>3</sub> 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 D<sub>3</sub> Forte 1000 mg/880 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 D<sub>3</sub> Forte 1000 mg/880 IU Chewable tablets have no known influence on your ability to drive and use machines.

### **Calciup D<sub>3</sub> Forte 1000 mg/880 IU Chewable tablets contain sodium, aspartame, sorbitol, isomalt, sucrose and benzyl alcohol.**

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

This medicine contains 1.00 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 up to 152.89 mg sorbitol (E420) in each chewable tablet. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine.

This medicine also contains isomalt (E953) 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 0.02 mg benzyl alcohol in each chewable tablet. Benzyl alcohol may cause allergic reactions.

### **3. How to take Calciup D<sub>3</sub> Forte 1000 mg/880 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.

#### **The recommended dose is:**

Adults and elderly take 1 chewable tablet daily (corresponding to 1,000 mg of calcium and 880 IU (International Units) of vitamin D<sub>3</sub>).

Pregnant women take only half a chewable tablet daily (corresponding to 500 mg of calcium and 440 IU (International Units) of vitamin D<sub>3</sub>). The daily dose of half a tablet must not be exceeded.

#### **Use in children and adolescents**

Calciup D<sub>3</sub> Forte 1000 mg/880 IU Chewable tablets must not be taken by children and adolescents below 18 years of age, also "Do not take Calciup D<sub>3</sub> Forte 1000 mg/880 IU Chewable tablets".

#### **Method of administration**

Oral use

The chewable tablet has to be chewed before it is swallowed. You can take Calciup D<sub>3</sub> Forte 1000 mg/880 IU Chewable tablets at any time, with or without food.

The tablet can be divided into equal doses.

#### **Duration of treatment**

Calciup D<sub>3</sub> Forte 1000 mg/880 IU Chewable tablets should be taken as long-term treatment. Talk to your doctor how long you should take Calciup D<sub>3</sub> Forte 1000 mg/880 IU Chewable tablets (see also section 2 Warnings and precautions).

#### **If you take more Calciup D<sub>3</sub> Forte 1000 mg/880 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 D<sub>3</sub> Forte 1000 mg/880 IU Chewable tablets may lead to symptoms such as feeling sick (nausea), vomiting, thirst or excessive thirst, increased urine output, dehydration or constipation (milk-alkali syndrome, see also section 4 Possible side effects).

#### **If you forget to take Calciup D<sub>3</sub> Forte 1000 mg/880 IU Chewable tablets**

If you forget to take Calciup D<sub>3</sub> Forte 1000 mg/880 IU Chewable tablets, 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 D<sub>3</sub> Forte 1000 mg/880 IU Chewable tablets**

If you wish to interrupt or prematurely discontinue the treatment, please consult your doctor.

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 D<sub>3</sub> Forte 1000 mg/880 IU Chewable tablets and contact a doctor immediately if you experience any of the following serious side effects:**

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

- severe allergic reactions: swelling of the face, lips, tongue or throat with sudden difficulty breathing and severe rash.
- frequent urge to urinate, continuing headache, continuing loss of appetite, nausea or vomiting, unusual tiredness or weakness, hypercalcaemia, alkalosis and renal impairment (milk-alkali syndrome).

**Other side effects reported are:**

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

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

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

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

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

- vomiting.

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

**5. How to store Calciup D<sub>3</sub> Forte 1000 mg/880 IU Chewable tablets**

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 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.

For tablet container:

After first opening: Keep the tablet container tightly closed in order to protect from moisture.

For strips: 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 D<sub>3</sub> Forte 1000 mg/880 IU Chewable tablets contain**

- The active substances are calcium and cholecalciferol. Each chewable tablet contains 1,000 mg calcium (as calcium carbonate) and 22 micrograms cholecalciferol (vitamin D<sub>3</sub> equivalent to 880 IU as concentrate powder form).
- 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 silicon dioxide colloidal). Flavour orange “CPB” also contains benzyl alcohol as part of the natural/nature identical mandarine oil.

**What Calciup D<sub>3</sub> Forte 1000 mg/880 IU Chewable tablets looks like and contents of the pack**

Round, white tablets with faultless surface and a break mark.

The chewable tablets are available in polypropylene tablet containers with polyethylene stoppers containing a desiccant or in strips of laminated aluminium paper foil.

Pack sizes:

Bottle: 10, 20, 28, 30, 40, 50, 56, 60, 90, 100 (bundling package 5x20) chewable tablets  
Strips: 10, 20, 28, 30, 40, 48, 56, 60, 60 (bundling package 2x30), 90, 90 (bundling package 3x30), 96, 100 (bundling package 5x20), 120 and multipack of 120 (2 packs of 60) 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, Georg-Kalb-Straße 5, 82049 Pullach i. Isartal, 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:**

Germany:	Calcium-Sandoz D Osteo intens 1.000 mg/880 I.E. Kautabletten
Czech Republic:	Calcium/Vitamin D3 Sandoz
Ireland:	Calciup D <sub>3</sub> Forte 1000 mg/880IU Chewable tablets
Poland:	Calcium Sandoz + Vitamin D3, 1000 mg + 880 IU, tabletki do rozgryzania i żucia
Romania:	Calciu Sandoz Osteo 1000 mg/880 UI comprimate masticabile (chewable tablets)
United Kingdom: (Northern Ireland)	Accrete D3 One a Day 1000 mg/880 IU Chewable Tablets

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