

## Evacal D3® 1500 mg/400 iu Chewable Tablets

calcium carbonate and colecalciferol

Package leaflet: Information for the user

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 have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse.

### What is in this leaflet

1. What Evacal D3® 1500 mg/400 iu Chewable Tablets are and what they are used for
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### 1 What Evacal D3® 1500 mg/400 iu Chewable Tablets are and what they are used for

Evacal D3® 1500 mg/400 iu Chewable Tablets are a calcium-vitamin D<sub>2</sub> supplement.

#### It is used

- to prevent and treat a lack of calcium and vitamin D in the elderly.
- for vitamin D- and calcium supplementation as supportive treatment of osteoporosis (brittle bones).

### 2 What you need to know before you take Evacal D3® 1500 mg/400 iu Chewable Tablets

#### Do not take Evacal D3® 1500 mg/400 iu Chewable Tablets

- if you are allergic to calcium, vitamin D, 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 your 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 restriction in movement 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

#### Warnings and precautions

- before taking <Calcium 600 mg / Vitamin D3 400 IU, chewable tablets>, calcium and alkali intake from other sources (e.g. foods, enriched foods or other medicinal products) should be considered. If high doses of calcium are given together with alkaline agents (such as carbonates), this can lead to milk-alkali syndrome (Burnett syndrome). Milk-alkali syndrome is a disorder of calcium metabolism with an increase in blood calcium levels. It can be triggered by the intake of very large quantities of milk and/or calcium carbonate from other sources or by excessive use of antacids (medicines to reduce too much acid in the stomach). This may lead to side effects, such as an increase in blood calcium levels (hypercalcaemia), metabolic alkalosis (a metabolic condition that causes an increase in blood pH), kidney failure and soft tissue calcification (see section 4.). Therefore, regular medical surveillance of blood calcium levels is required.
- 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 dosage or discontinue the treatment.
- if you are simultaneously being treated with cardiac glycosides or thiazide diuretics (water tablets) for heart problems the levels of calcium in your blood and urine and your kidney function have to be monitored regularly. Depending on your blood levels your doctor might reduce the dosage or discontinue the treatment.
- if you suffer from kidney problems you have to take Evacal D3® 1500 mg/400 iu Chewable Tablets with special care. Your calcium and phosphate levels of the blood and urine have to be checked. If you suffer from severe kidney problems, use other forms of vitamin D than colecalciferol.
- take additional supplementation of calcium and vitamin D only under medical

supervision and your doctor will require frequent monitoring of the calcium levels in the blood and urine.

- take special care when taking Evacal D3® 1500 mg/400 iu Chewable Tablets if you suffer from sarcoidosis (an immune system disorder which may affect your liver, lung, skin or lymph nodes). There is a risk that the effect of this medicinal product 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.
- if you are immobile and are suffering from osteoporosis this medicinal product has to be used with special care, as the level of calcium in your blood might increase.

If any of the above apply to you, talk to your doctor or pharmacist before taking Evacal D3® 1500 mg/400 iu Chewable Tablets.

#### Children under 12 years

Evacal D3® 1500 mg/400 iu Chewable Tablets are not intended for use in children under 12 years.

#### Other medicines and Evacal D3® 1500 mg/400 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), changes in the way the heart beats (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 drug class (also called water tablets), the blood calcium level should be regularly monitored since thiazides decrease the amount of calcium disposed of in the urine.
- The absorption and thus also the effectiveness of certain antibiotics (called tetracyclines) are decreased by the simultaneous administration of Evacal D3® 1500 mg/400 iu Chewable Tablets. These drugs should be taken at least 2 hours before or 4-6 hours after Evacal D3® 1500 mg/400 iu Chewable Tablets.
- Furthermore, other medicines such as sodium fluoride (used to strengthen the tooth enamel or to treat osteoporosis) and bisphosphonate (used to treat osteoporosis) drugs are affected by interactions. These products should therefore be taken at least 3 hours before Evacal D3® 1500 mg/400 iu Chewable Tablets.
- As long an interval as possible should be left between the administration of cholestyramine (a product to lower raised cholesterol levels) or laxatives such as liquid paraffin and Evacal D3® 1500 mg/400 iu Chewable Tablets since otherwise vitamin D is not absorbed properly.
- The simultaneous administration of Evacal D3® 1500 mg/400 iu Chewable Tablets and 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 Evacal D3® 1500 mg/400 iu Chewable Tablets and glucocorticoids (e.g. cortisone) can result in a reduction in the effect of vitamin D and 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 can reduce the effect of levothyroxine (used to treat thyroid deficiency). For this reason, levothyroxine should be taken at least four hours before or four hours after Evacal D3® 1500 mg/400 iu Chewable Tablets.
- The effect of quinolone antibiotics may be reduced if taken at the same time as calcium. Take quinolone antibiotics two hours before or six hours after taking Evacal D3® 1500 mg/400 iu Chewable Tablets.

#### Evacal D3® 1500 mg/400 iu Chewable Tablets with food and drink

You can take Evacal D3® 1500 mg/400 iu Chewable Tablets at any time, with or without food.

Please notice that oxalic acid (contained in spinach and rhubarb) and phytic acid (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 patients should not take medicinal products that contain calcium.

#### Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, Evacal D3® 1500 mg/400 iu Chewable Tablets should only be used under medical supervision. Ask your doctor or pharmacist for advice before taking this medicine.

If you are pregnant you may use Evacal D3® 1500 mg/400 iu Chewable Tablets in case of a calcium and vitamin D deficiency. The daily dose of 1 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>2</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.

Evacal D3® 1500 mg/400 iu Chewable Tablets can be used during breast-feeding. As calcium and vitamin D and its metabolites also pass into breast-milk check with your doctor first if your child receives any other products containing vitamin D.

#### Driving and using machines

Evacal D3® 1500 mg/400 iu Chewable Tablets have no influence on your ability to drive and use machines.

#### Evacal D3® 1500 mg/400 iu Chewable Tablets contains

- aspartame (E951), a source of phenylalanine which may be harmful for people with phenylketonuria
- sorbitol (E420), 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.

### 3 How to take Evacal D3® 1500 mg/400 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.

#### Dose

If not told otherwise by your doctor the recommended dose is:  
Adults, elderly and children over 12 years of age take 2 chewable tablets daily (corresponding to 1,200 mg of calcium and 800 IU (International Units) of vitamin D<sub>3</sub>), preferably one tablet each morning and evening. Pregnant women take 1 chewable tablet daily (corresponding to 600 mg of calcium and 400 IU (International Units) of vitamin D<sub>3</sub>). The daily dose of 1 tablet must not be exceeded.

#### Method of administration

The tablet has to be chewed before it is swallowed. It should be taken at any time, with or without food.

#### Duration of treatment

Evacal D3® 1500 mg/400 iu Chewable Tablets should be taken as long-term treatment. Talk to your doctor about how long you should take this medicine for (see also section 2, Warnings and precautions).

#### If you take more Evacal D3® 1500 mg/400 iu Chewable Tablets than you should

Overdose of Evacal D3® 1500 mg/400 iu Chewable Tablets may lead to symptoms such as feeling sick (nausea), vomiting, thirst or excessive thirst, increased urine output, depletion of body fluids or constipation. If an overdose is suspected, contact your doctor or pharmacist immediately.

#### If you forget to take Evacal D3® 1500 mg/400 iu Chewable Tablets

If you forget to take Evacal D3® 1500 mg/400 iu Chewable Tablets, take it as soon as you remember. However, do not take a double dose to make up for a forgotten tablet.

#### If you stop taking Evacal D3® 1500 mg/400 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 Evacal D3® 1500 mg/400 iu Chewable Tablets and contact a doctor immediately

- if you experience the following allergic reaction (not known as frequency cannot be estimated from the available data):
- swelling of the face, lips, tongue or throat with sudden difficulty breathing and severe rash.

The 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).
- rash, itching, hives.

Not Known: frequency can not be estimated from the available data

- If you have impaired renal function, you may be at risk of increased amounts of phosphate in the blood, renal stone formation and increased amounts of calcium in the kidneys.
- calcium metabolic disorder (milk-alkali syndrome) with an increase in blood calcium levels (hypercalcaemia), too little acid in the blood (metabolic alkalosis), kidney failure and soft tissue calcification.

#### 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 Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)  
By reporting side effects you can help provide more information on the safety of this medicine.

### 5 How to store Evacal D3® 1500 mg/400 iu Chewable Tablets

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

Do not use this medicine after the expiry date (EXP) which is stated on the carton and on the tablet container or on the laminated aluminium paper foil. The expiry date (EXP) refers to the last day of that month.

#### For tablet container:

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 to protect the environment.

### 6 Contents of the pack and other information

#### What Evacal D3® 1500 mg/400 iu Chewable Tablets contains

- The active substances are calcium and colecalciferol. Each chewable tablet contains 1,500 mg of calcium carbonate (equivalent to 600 mg of calcium) and 4.0 mg of colecalciferol concentrate (powder form) (equivalent to 10 micrograms of colecalciferol = 400 IU of vitamin D<sub>3</sub>).
- The other ingredients are isomalt (E953), xylitol, sorbitol (E420), citric acid, anhydrous, sodium dihydrogen citrate, magnesium stearate, carmellose sodium, flavour tutti frutti, silica, colloidal hydrated, aspartame (E951), acesulfam potassium, sodium ascorbate, all-rac-alpha-tocopherol, modified (maize) starch, sucrose, triglycerides medium chain and silicon dioxide colloidal.

#### What Evacal D3® 1500 mg/400 iu Chewable Tablets looks like and contents of the pack

Evacal D3® 1500 mg/400 iu Chewable Tablets are round, white tablets.

The chewable tablets are available in polypropylene tablet containers with polyethylene stoppers containing a desiccant in the following package sizes:  
10, 20, 30, 50, 56, 60, 90, 100, 112, 120, bundling pack containing 200 (2 packs of 100) chewable tablets.

The chewable tablets are available in strips of laminated aluminium paper foil in the following package sizes:

10, 20, 30, 50, 56, 60, 90, 100, 112, bundling pack containing 112 (2 packs of 56), multipack containing 112 (2 packs of 56), 120, bundling pack containing 120 (2 packs of 60), bundling pack containing 200 (2 packs of 100) chewable tablets.

Not all pack sizes may be marketed.

#### Marketing Authorisation Holder

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#### Manufacturer

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