Package leaflet: Information for the user

Calcium/Cholecalciferol Hermes Pharma 500 mg / 1000 IU, chewable tablets
calcium / cholecalciferol (vitamin D_3)

Read all of this leaflet carefully before you start taking 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

1. What <Invented name> are and what they are used for

<Invented name> contains calcium and cholecalciferol (vitamin D3), which are important substances in bone formation.
It is used
- to prevent a combined calcium and vitamin D deficiency in adult patients at risk (e.g. postmenopausal women or the elderly)
- to correct a combined calcium and vitamin D deficiency in adults
- as a supplement to specific treatment of osteoporosis (brittle bones) of adult patients who are at risk of vitamin D and calcium deficiency.

Therapy is only advisable if a sufficient calcium and vitamin D supply cannot be achieved by nutrition and sunlight.

2. What you need to know before you take <Invented name>

Do not take <Invented name>

- if you are allergic to calcium, vitamin D_3 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 a disease and/or condition, which lead to high levels of calcium in your blood (hypercalcaemia) and/or high levels of calcium in your urine (hypercalciuria), e.g., overactive parathyroid glands (hyperparathyroidism), bone marrow cancer (myeloma), 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 with accompanying severe and progressive overactive parathyroid glands (hyperparathyroidism) your doctor will consider other forms of vitamin D which may be more suitable for you.

Warnings and precautions
Talk to your doctor or pharmacist before taking <Invented name>

- if you are on long-term treatment, especially if you also take diuretics (used in the treatment of high blood pressure or oedema) or cardiac glycosides (used to treat heart disorders).
- if you have parathyroid hormone imbalance (pseudohypoparathyroidism).
- if you have impaired renal function.
- if you take other products containing calcium and vitamin D. Additional doses of calcium and vitamin D should be taken under close medical supervision.
- if you have sarcoidosis (an immune system disorder that may increase vitamin D levels in the body).
- if you have osteoporosis and at the same time are unable to move around.

Children and adolescents
<Invented name> are not intended for use in children and adolescents.

Other medicines and <Invented name>
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 or loop diuretic, amiloride)
- fluid overload conditions such as heart failure, nephrotic syndrome or cirrhosis (loop diuretics, amiloride)
- heart problems (cardiac glycosides such as digoxin)
- epilepsy (phenytoin, carbamazepine)
- sleeping problems (hypnotics like barbiturates)
- inflammatory conditions/suppression of immunity (corticosteroids)
- bacterial or fungal infections (rifampicin, actinomycin and imidazole antimycotics)
- increased stomach acidity (calcium-containing antacids).

Phosphate-containing medicines should be avoided as this can reduce the amount of phosphate absorbed.
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 three hours before you take <Invented name>.
- infection (quinolones) you should take these two hours before or six hours after taking <Invented name>.
- infection (tetracyclines) you should take these two hours before or four to six hours after taking <Invented name>.
- dental caries (sodium fluoride) you should take these medicines at least three hours before taking <Invented name>.
- hypothyroidism (levothyroxine) you should separate the intake with <Invented name> by at least four hours.
- neutralisation of stomach acidity (antacids) you should take these medicines at least four hours before taking <Invented name>.
- fungal infections of the skin (ketokonazole) you should take these at least two hours before or after taking <Invented name>.

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 <Invented name> by at least two hours.

Treatment with orlistat (medicine against obesity), ion exchange resins such as cholestyramine (a product to lower raised cholesterol levels) or laxatives such as liquid paraffin (medicine against constipation) may possibly impair the absorption of fat-soluble vitamins (e.g. vitamin D3). A time interval as long as possible between the administration of these medicines and <invented name> is recommended..
Calcium salts can reduce absorption of estramustine (used to treat cancer of the prostate gland). As long an interval as possible should be left between the administration of <Invented name> and estramustine.

<Invented name> with food and drink
You can take <Invented name> at any time, with or without food.
The effect can be influenced 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 <Invented name> if you have eaten food with high content of oxalic acid or phytic acid.

Pregnancy, breast-feeding and fertility
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.

Pregnancy
<Invented name> is not recommended during pregnancy and lactation unless your doctor has diagnosed a combined calcium and vitamin D deficiency. Where there is a calcium and vitamin D deficiency, the recommended dose is dependent on national guidelines, however, the maximum dose should not be higher than 2,500 mg calcium and 4000 IU (100 µg) vitamin D per day.

Overdoses of vitamin D in pregnancy must be avoided, as prolonged elevated calcium levels in the blood may have negative effects on the unborn child

Breast-feeding
<Invented name> is not recommended during breast-feeding unless your doctor has diagnosed a combined calcium and vitamin D deficiency. As calcium and vitamin D pass into breast-milk, check with your doctor first if your child receives any other products containing vitamin D. This should be considered when giving additional vitamin D to the child.

Driving and using machines
<Invented name> have no influence on your ability to drive and use machines.

<Invented name> contains
- 0.50 mg of aspartame (E951), 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.
- 60.41 mg of sorbitol (E420), which is equivalent to xx mg/kg. Sorbitol is a source of fructose. If your doctor has told you that you 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 take or receive this medicine. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.
- 185 mg of isomalt (E953) and 1.925 mg of sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine. Sucrose may be harmful to the teeth. Isomalt may have a mild laxative effect.
- 0.01 mg of benzyl alcohol. Ask your doctor or pharmacist for advice if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called “metabolic acidosis”).

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

3. How to take <Invented name>

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Dose
The recommended dose is:
Adults and elderly take 1 chewable tablet daily (corresponding to 500 mg of calcium and 1000 IU (International Units) of vitamin D_3)

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

You should give attention to a sufficient daily intake of calcium by nutrition (i.e. milk products, vegetables, mineral water).

Duration of treatment
<Invented name> 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 <Invented name> than you should
Overdose of <Invented name> 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 <Invented name>
If you forget to take <Invented name>, 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 <Invented name>
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 <Invented name> and contact a doctor immediately if you experience the following allergic reaction (not known as frequency cannot be estimated from the available data):
- Hypersensitivity reactions such as swelling of the face, lips, tongue or throat with sudden difficulty breathing and severe rash.

The other side effects reported are:

Rare:
- feeling sick (nausea), diarrhoea, abdominal pain, constipation, wind, bloating (abdominal distension).
- rash, itching, hives.
  (Rare side effect, may affect up to 1 in 1,000 people)

Uncommon:
- high levels of calcium in your blood (hypercalcaemia) or urine (hypercalciuria).
  (*Uncommon side effect*, may affect up to 1 in 100 people)

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.
[To be completed nationally]

5. How to store <Invented name>

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 laminated aluminium paper foil or on the polypropylen tubes. The expiry date refers to the last day of that month.

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 <Invented name> contain
- The active substances are calcium and cholecalciferol. Each chewable tablet contains 500 mg calcium (as calcium carbonate) and 25 micrograms cholecalciferol (vitamin D_3, equivalent to 1000 IU) as cholecalciferol-concentrate (powder form).
- The other ingredients are isomalt (E953), xylitol, sorbitol (E420), citric acid, monosodium citrate, magnesium stearate, carmellose sodium, flavour Orange “CPB”, flavour Orange “CVT”, 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 <Invented name> look like and contents of the pack
<Invented name> are round, white tablets 18 millimetres in diameter.

The chewable tablets are available in strips of laminated aluminium paper foil or alternatively in polypropylene tubes with a polyethylene stopper containing a desiccant in the following package sizes:
30 and 90 (3x30) chewable tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
[To be completed nationally]

{Name and address}
{tel}
{fax}
{e-mail}

Manufacturer
Hermes Pharma GmbH
Hans-Urmiller-Ring 52
82515 Wolfratshausen
Germany

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

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