

PATIENT INFORMATION LEAFLET

CALOSHELL®-500 TABLETS

calcium / colecalciferol

Read all of this leaflet carefully 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.
- You must talk to a doctor if you do not feel better or if you feel worse after two weeks.
- 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.

In this leaflet:

1. What Caloshell-500 is and what it is used for
2. What you need to know before you take Caloshell-500
3. How to take Caloshell-500
4. Possible side effects
5. How to store Caloshell-500
6. Contents of the pack and other information

1. WHAT CALOSHELL-500 IS AND WHAT IT IS USED FOR

Caloshell-500 Tablets containing calcium and vitamin D₃ which are both important substances in bone formation. Both are found in the diet and vitamin D is also produced in the skin after exposure to the sun.

Caloshell-500 is used to treat and prevent vitamin D/calcium deficiency, which may occur when your diet or lifestyle does not provide enough, or when body requirements are increased. This medicine may also be prescribed or recommended for certain bone conditions, for example osteoporosis, or during pregnancy.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CALOSHELL-500

Do not take Caloshell-500 Tablets if you:

- are allergic to calcium, vitamin D, or any of the other ingredients of this medicine (listed in section 6).
- have severe kidney problems
- have a condition that causes excessive amounts of calcium in your blood or urine (hypercalcaemia or hypercalciuria) e.g.
 - renal (kidney) failure
 - cancer that has affected your bones
- have excessive amounts of Vitamin D in your blood
- have kidney stones.

Warnings and precautions

Talk to your doctor or pharmacist before taking Caloshell-500:

- if you have **osteoporosis** (brittle bones) and are also unable to move around
- if you are on long term treatment, especially if you are taking medicines for a **heart disorder** (cardiac glycosides), or **diuretics** (used in the treatment of high blood pressure or oedema)
- if you have signs of **impaired renal function** or a high tendency to **kidney stone** (calculus) formation
- if you have **cancer** or any other conditions that may have affected your bones.
- if you have **sarcoidosis** (an immune system disorder which may cause increased levels of vitamin D in the body).

If you have any of the following conditions your serum calcium or phosphate levels, or urinary calcium excretion must be monitored. Caloshell-500 should be taken under close medical supervision.

- **sarcoidosis** (an immune system disorder which may affect your liver, lungs, skin or lymph nodes)
- **kidney** problems
- you are on **long-term treatment** with Caloshell-500
- you are already taking **additional doses** of **calcium** or **vitamin D**.

If you have increased calcium levels in the blood or develop signs of kidney problems, the dose of Caloshell-500 should be reduced or the treatment discontinued.

Other medicines and Caloshell-500

Please inform your doctor or pharmacist if you are taking or have recently taken or might take any other medicines.

In particular, the following medicines may interact with Caloshell-500 tablets:

- **thiazide diuretics** (water tablets); your serum calcium levels should be monitored regularly.
- **cardiac glycosides** (heart medicines); you should be monitored by electrocardiogram (ECG) and your serum calcium levels measured.
- **tetracycline antibiotics**; these should be taken at least two hours before, or four to six hours afterwards. Calcium carbonate may interfere with the absorption of tetracycline preparations if taken at the same time.
- **levothyroxine (hormone used to treat thyroid deficiency)**; these should be taken at least four hours before or after taking Caloshell-500.
- **quinolone antibiotics (ciprofloxacin, iomefloxacin, norfloxacin, sparfloxacin)**: the effect of these medicines may be reduced if taken at the same time as calcium. Take quinolone antibiotics two hours before or six hours after taking Caloshell-500.
- **bisphosphonates**; should be taken at least one hour before Caloshell-500.
- Calcium salts may decrease the absorption of **iron, zinc and strontium ranelate**. Consequently, iron, zinc or strontium ranelate preparations should be taken at least two hours before or after Caloshell-500.
- **Orlistat** (used to treat obesity) may disturb the absorption of fat-soluble vitamins, e.g. vitamin D3.

If you are taking any of the above mentioned medicines, your doctor will give you further instructions.

Taking Caloshell-500 with food and drink

Caloshell-500 can be taken with or without food and drink.

Pregnancy and breastfeeding

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 Caloshell-500.

If you are pregnant, you may use this medicine in case of a calcium and vitamin D deficiency. During pregnancy you should not take more than 2500 mg calcium and 4000 IU vitamin D per day, as overdoses may harm the unborn child.

Caloshell-500 can be used during breast-feeding. Calcium and vitamin D₃ pass into breast milk. This should be considered when giving additional vitamin D to the child.

Driving and using machines

Caloshell-500 has no known influence on the ability to drive or use machines.

3. HOW TO TAKE CALOSHELL-500 TABLETS

Always take Caloshell-500 exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Dosage

The recommended dose is two or three tablets a day, preferably one tablet in the morning, one at midday and one in the evening.

Children

The recommended dose is two tablets a day, preferably one tablet in the morning and one tablet in the evening.

If you take more than you should

If you have taken more Caloshell-500 than you should, talk to your doctor or pharmacist immediately.

If you forget to take Caloshell-500 Tablets

Do not take a double dose to make up for a forgotten tablet.

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 your medicine and see a doctor immediately if you experience:

- Frequent urge to urinate
- Headache
- Loss of appetite, nausea or vomiting
- Unusual tiredness or weakness, along with elevated levels of calcium in the blood and kidney impairment.

Side effects include:

Uncommon side effects (may affect up to 1 in 100 people):

- **excessive amounts of calcium in your blood** (hypercalcaemia) **or in your urine** (hypercalcuria) may occur with large doses

Rare side effects (may affect up to 1 in 1,000 people):

- nausea
- stomach ache
- constipation
- heartburn (dyspepsia)
- diarrhoea
- wind (flatulence)
- rash
- hives
- itching

Very rare side-effects (may affect up to 1 in 10,000 people):

- Milk alkali syndrome (also called Burnett's Syndrome and usually only seen when excessive amounts of calcium have been ingested), symptoms are frequent urge to urinate, headache, loss of appetite, nausea or vomiting, unusual tiredness or weakness, along with elevated levels of calcium in the blood and kidney impairment.

Side effects with frequency not known (cannot be estimated from the available data):

- Hypersensitivity reactions such as swelling of the face, tongue, lips (angioedema) or swelling of the throat (laryngeal oedema).
- 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.

5. HOW TO STORE CALOSHELL-500 TABLETS

Keep out of the sight and reach of children.

Do not use Caloshell-500 after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month. If the tablets have changed shape or colour do not use.

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 Caloshell-500 Tablets contain

The active ingredients in each tablet are: Calcium Carbonate [Oyster Shell], Colecalciferol [Vitamin D3]

The other ingredients are:

Starch USP NF

Lactose Monohydrate

Starch USPNF

Sodium Starch Glycolate BP

Povidone USP

Methylparaben BP

Purified Water BP

Magnesium Stearate BP

Talc BP

Sodium Lauryl Sulphate

What Caloshell-500 look like and contents of the pack

The tablets are round, white, uncoated convex and orange flavoured; they may have small specks.

The tablets are packed in white, plastic bottles of 100 tablets.

Marketing Authorisation Holder:

Emcure Pharmaceuticals Limited

Manufacturer:

Emcure Pharmaceuticals Limited.

Lane No. 3, Phase-II, SIDCO,

Bari-Brahmana, Jammu - 181 133, INDIA

Additional Information

Caloshell-500 are a combination of calcium and vitamin D designed to keep bones healthy. Calcium is an essential component of bones while vitamin D plays an important role in the absorption of calcium from food.

Requirements for calcium increase with age and, although many people obtain enough calcium from their diet, some people may require a supplement in order that their body has all the calcium it needs to maintain healthy bones. Vitamin D is produced largely from the action of sunlight. Certain foodstuffs do contain vitamin D in reasonable amounts but it is not always possible to obtain all the vitamin D you need from your diet. People who do not get out and about, for instance those who are housebound or people living in nursing and residential homes, may not receive all the vitamin D they need.

People with diets and lifestyles that mean they will obtain less than the recommended intake of calcium and vitamin D are at risk of weakened bones. Prolonged lack of adequate calcium and vitamin D intake can lead to the development of osteoporosis, a condition where bones become weak

to a level that minimal trauma (for example, a fall) can result in a fracture, most typically at the hip, spine or wrist.

Caloshell-500 has been designed to give people, whose intakes of calcium and vitamin D are low, a boost to the recommended amounts.

Maintaining healthy bones and helping to avoid osteoporosis is an important issue for many people. There are many ways that people can help themselves: regular exercise, a balanced diet with an adequate intake of calcium and vitamin D and, for some people, advice on how to prevent falls which may lead to fracture.