

PACKAGE LEAFLET: INFORMATION FOR THE USER

Calceos 500mg/400IU Chewable Tablets calcium and colecalciferol (vitamin D₃)

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, pharmacist or nurse has 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, pharmacist or nurse. 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 after taking this medicine.

What is in this leaflet:

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1. What Calceos 500mg/400IU Chewable Tablets are and what they are used for

Calceos 500mg/400IU Chewable Tablets belong to a group of medicines which act on the calcium and vitamin D balance in your body. Calceos 500mg/400IU Chewable Tablets contain the active substances calcium carbonate and colecalciferol (vitamin D₃). Calceos is recommended for the treatment of calcium and vitamin D deficiency in elderly patients, that has been diagnosed by a doctor. It can be used in combination with other medicines for the treatment of osteoporosis in adults and elderly patients. Calceos can also be taken by adults and elderly patients who have been identified by their doctor as having a high risk of developing a deficiency of both calcium and vitamin D.

You must talk to a doctor if you do not feel better or if you feel worse after taking this medicine.

2. What you need to know before you take Calceos 500mg/400IU Chewable Tablets

Do not take Calceos 500mg/400IU Chewable Tablets

- if you are allergic to calcium or vitamin D or any of the other ingredients of this medicine (listed in section 6)
- if you are allergic (hypersensitive) to peanut or soya (this product contains soybean oil)
- if you have high blood calcium levels
- if you have high urine calcium levels
- if you suffer from severe kidney problems
- if you have kidney stones

- if you have too much vitamin D in your body
- if you have any type of cancer of the bone
- if you are immobile for a great part of the day

Talk to your doctor before taking this medicine if any of the above apply to you.

Warnings and precautions

It may be necessary to determine the levels of calcium and vitamin D in your blood or urine, or both of these, before you start to take Calceos 500mg/400IU Chewable Tablets.

Talk to your doctor or pharmacist before taking Calceos 500mg/400IU Chewable Tablets:

- if you are on long-term treatment, especially if you are also elderly, take diuretics (used in treatment of high blood pressure or oedema) or take cardiac glycosides (used to treat heart disorders).
- if you have sarcoidosis (inflammation that produces lumps of cells in various organs in the body, your doctor will be able to tell you if you have this).
- if you have problems with your kidneys.

In those cases, it may also be necessary for the levels of calcium and vitamin D in your blood or urine, or both of these, to be monitored under medical supervision during treatment with Calceos 500mg/400IU Chewable Tablets.

Children and adolescents

This medicine is only suitable for use in adults.

Other medicines and Calceos 500mg/400IU Chewable Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes those medicines obtained without a prescription.

This is especially important if you are taking:

- other medications containing vitamin D or calcium.
- other medications containing fluoride or iron (calcium may impair the absorption of these medicines), Calceos 500mg/400IU Chewable Tablets should not be taken within three hours of taking these medicines.
- cardiac glycosides, for example digitoxin and digoxin (used to treat certain heart conditions).
- thiazide diuretics (used in treatment of high blood pressure and oedema).
- tetracycline antibiotics (calcium may impair the absorption of these medicines), Calceos 500mg/400IU Chewable Tablets should not be taken within three hours of taking this medicine.
- disodium etidronate used to treat bone disorders (calcium may impair the absorption of this medicine), Calceos 500mg/400IU Chewable Tablets should not be taken within three hours of taking this medicine.
- strontium containing medicines (used to treat osteoporosis) as calcium may reduce the effects of these. Calceos 500mg/400IU Chewable Tablets should not be taken at the same time as this medicine.
- estramustine (a medicine used in chemotherapy) and levothyroxine (used to treat thyroid deficiency) as calcium may reduce the effects of these medicines. For this reason, they should be taken at least two hours before or after Calceos 500mg/400IU Chewable Tablets.
- orlistat (a medicine used to treat obesity) as it may reduce the amount of vitamin D3 you absorb.

It may still be safe for you to take Calceos 500mg/400IU Chewable Tablets; your doctor or pharmacist will be able to advise you further.

Calceos 500mg/400IU Chewable Tablets with food and drink

This product is likely to interact with some foods, for example those containing oxalic acid (e.g. spinach, rhubarb, sorrel, cocoa, tea), phosphate (e.g. ham, sausages, cheese spread) or phytic acid (e.g. pulses, whole cereals, chocolate). It is therefore recommended that Calceos 500mg/400IU Chewable Tablets should not be taken at the same time (e.g. two hours before or after) as meals containing these types of food.

Pregnancy and breast-feeding

During pregnancy and breast-feeding, the daily dose should not exceed 1500mg of calcium and 600IU of vitamin D3 i.e. one tablet a day.

Calceos 500mg/400IU Chewable Tablets 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.

Ask your doctor or pharmacist for advice before taking any medicine during pregnancy or while breast-feeding.

Driving and using machines

Calceos 500mg/400IU Chewable Tablets are not expected to affect your ability to drive or use machines.

Important information about some of the ingredients of Calceos 500mg/400IU Chewable Tablets

This medicine contains 475mg sorbitol in each chewable tablet. 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 this medicine.

Calceos 500mg/400IU Chewable Tablets contain sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. May be harmful to the teeth.

Calceos 500mg/400IU Chewable Tablets contain soybean oil. If you are allergic to peanut or soya, do not take this medicinal product. Talk to your doctor for further advice.

3. How to take Calceos 500mg/400IU Chewable Tablets

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

The recommended dose for adults and the elderly is one tablet, to be taken twice a day. Chew the tablets completely before swallowing. Then drink a glass of water.

If you take more Calceos 500mg/400IU Chewable Tablets than you should

If you take too many tablets, contact your nearest hospital casualty department or doctor immediately. Take this leaflet and any remaining tablets with you to show the doctor. If you take too many tablets the following symptoms could occur: nausea (feeling sick), vomiting, severe thirst, constipation, lack or loss of appetite, excessive urination, dehydration, hypertension (high blood pressure), vasomotor disorders (resulting in dilation and constriction of the blood vessels).

If you forget to take Calceos 500mg/400IU Chewable Tablets

If you forget to take your tablet, take it as soon as you remember and then continue with the next dose as instructed. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Uncommon side effect (may affect up to 1 in 100 people): excess calcium levels in the blood or urine.

Rare side effects (may affect up to 1 in 1,000 people): constipation, flatulence, feeling sick (nausea), abdominal pain, diarrhoea, itching, skin rashes and hives (urticaria).

Cases of serious allergic (hypersensitivity) reactions such as swelling of the face, lips, tongue or throat have been reported.

Due to the presence of sucrose, long-term use (for two weeks or more) may be harmful to teeth.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Calceos 500mg/400IU Chewable Tablets

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

The stopper contains small granules of silica gel to keep the tablets dry. Keep the stopper out of the sight and reach of children. Do not swallow the silica gel granules.

Do not use this medicine after the expiry date which is stated on the carton and container. The expiry date refers to the last day of that month.

Store in the original packaging in order to protect the tablets from moisture.

Do not use this medicine if you notice that the pack or any of the tablets are damaged.

Do not store above 25°C.

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 Calceos 500mg/400IU Chewable Tablets contain

The active substances are calcium carbonate and colecalciferol (vitamin D₃). Each chewable tablet contains 1250mg of calcium carbonate (equivalent to 500mg elemental calcium) and 10 micrograms colecalciferol (equivalent to 400IU vitamin D₃).

The other ingredients are: xylitol, sorbitol (E420), povidone, magnesium stearate, alpha tocopherol, partially hydrogenated soybean oil, gelatin, sucrose, corn starch and lemon flavour (containing essential oils of lemon, orange and litsea cubeba, maltodextrin, acacia gum and sodium citrate).

What Calceos 500mg/400IU Chewable Tablets look like and contents of the pack

Calceos 500mg/400IU Chewable Tablets are greyish white, square chewable tablets.

Calceos 500mg/400IU Chewable Tablets are available in packs of 60 tablets. Each pack of 60 tablets contains 4 tubes each containing 15 tablets.

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder:

Laboratoire Innotech International, 22 avenue Aristide Briand, 94110 Arcueil, France.

Manufacturer:

Innothéra Chouzy, Rue René Chantereau, Chouzy-sur-Cisse, 41150 Valloire-sur-Cisse, France.

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