


Désignation:	CALCEOS GB CRUANAS 01-18	Code :	532619-0118
Format à plat :	170X270 MM	Format plié :	N/A
Impression R°:	NOIR	Impression V°:	NOIR
Papier:	60 G	Edition :	1
 Tonnellier	INNOTHERA		

PACKAGE LEAFLET: INFORMATION FOR THE USER

CALCEOS® 500mg/400IU CHEWABLE TABLETS

(calcium carbonate and colecalciferol (vitamin D₃))

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to take Calceos 500mg/400IU Chewable Tablets carefully to get the best results from them.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.
- 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.

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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 500mg/400IU Chewable Tablets are recommended for the treatment of calcium and vitamin D deficiency in the elderly, for use in combination with other medicines for the treatment of osteoporosis and when a risk of deficiency of calcium and vitamin D is suspected.

2. BEFORE YOU TAKE CALCEOS 500mg/400IU CHEWABLE TABLETS

Do not take Calceos 500mg/400IU Chewable Tablets

- if you are allergic (hypersensitive) to calcium or vitamin D or any of the other ingredients in Calceos 500mg/400IU Chewable Tablets
 - 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 product if any of the above apply to you.

Take special care with 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). Please consult your doctor.
- if you are taking other products containing calcium and/or vitamin D, even those you may have bought yourself without prescription.
- if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- 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 do.
- if you have problems with your kidneys.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any medicines, including 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.

Taking 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

Calceos 500mg/400IU Chewable Tablets contain sorbitol (E420) 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.

Calceos 500mg/400IU Chewable Tablets contain soybean oil. If you are allergic (hypersensitive) 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

Chew the tablets completely before swallowing. Then drink a glass of water.

The usual dose for adults and the elderly is one tablet, to be taken twice a day.

If this product has been prescribed by your doctor, the label on the carton will tell you how many tablets you should take and when. Always take Calceos 500mg/400IU Chewable Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

While you are taking these tablets, your doctor may want to carry out regular tests on your blood and urine.

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 product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Calceos 500mg/400IU Chewable Tablets can cause side effects, although not everybody gets them.

Uncommon side effect (affecting 1 to 10 users in 1,000): excess calcium levels in the blood or urine.

Rare side effects (affecting 1 to 10 users in 10,000): 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 at: 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 CALCEOS 500mg/400IU CHEWABLE TABLETS

Keep out of the reach and sight 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 Calceos 500mg/400IU Chewable Tablets 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 store above 25°C.

Do not take Calceos 500mg/400IU Chewable Tablets if you notice that the pack or any of the tablets are damaged.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Calceos 500mg/400IU Chewable Tablets contain

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

The other ingredients in the tablet 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.

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Distributed by:

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BT63 5UA, UK.

This leaflet was last revised in 10/2019.

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