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	NOTI CALCEOS GB cruanas 11-25 (GRANDE BRETAGNE)	535451-11-25 VERSION 3	
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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:

1. What Calceos 500mg/400IU Chewable Tablets are and what they are used for
2. What you need to know before you take Calceos 500mg/400IU Chewable Tablets
3. How to take Calceos 500mg/400IU Chewable Tablets
4. Possible side effects
5. How to store Calceos 500mg/400IU Chewable Tablets
6. Contents of the pack and other information

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 (a condition where bone mass decreases and bone brittleness increases) 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 (hypercalcaemia)
- if you have high urine calcium levels (hypercalciuria)
- if you suffer from severe kidney problems
- if you have kidney stones or calcium deposits in your kidneys
- if you have too much vitamin D in your body
- if you have a condition that leads to hypercalcaemia and/or hypercalciuria (e.g., overactive parathyroid glands, a disease of the bone marrow (myeloma), a malignant bone tumour (bone metastases))

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

Warnings and precautions

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

- if you are suffering from sarcoidosis, a disease with most commonly symptoms such as tiredness, increase of nodules size and inflammation of lungs and other organs.
- if you are suffering from kidney disease (kidney insufficiency).
- if you are already taking additional doses of calcium (e.g. nutritional supplements or foods enriched with calcium) and are using medicinal products containing carbonate (e.g. so-called antacids) at the same time, the calcium content of the serum and the urine should be monitored.
- if you have a long period of immobility and if you have a high concentration of calcium in blood and/or urine. Your doctor will allow you to take this medicine when you walk again,

- if you have long term treatment, regular blood and urine tests are necessary to monitor calcium levels. This monitoring is particularly important in the elderly and where treatment is being taken at the same time as cardiac glycosides (e.g. digoxin) or diuretics. Depending upon the result, your doctor may decide to reduce or even stop your treatment,
- if you take other medicines or other products containing calcium and/or vitamin D. High levels of calcium and vitamin D may be harmful to health.

If in doubt, ask your doctor or pharmacist for advice.

Children and adolescents

Do not give this medicine to children and adolescents because there is no relevant use of CALCEOS in the paediatric population.

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.
- Digoxin (medicine used to treat heart problems), as they may cause more side effects.
- Bisphosphonates, or strontium containing medicines (used in osteoporosis).
- Antibiotics (medicines used to treat infections due to bacteria); oral use tetracycline, rifampicin and some fluoroquinolones (ciprofloxacin and norfloxacin).
- Dolutegravir (a medicine used to treat HIV infection).
- Medicines or supplements containing iron or zinc.
- Estramustine (a medicine used to treat some prostate cancers).
- Thyroid hormones, used in cases of thyroid disease.
- Carbamazepine, fosphenytoin, phenobarbital, phenytoin, primidone: medicines used to treat epileptic seizures.
- Orlistat (a medicine used to treat obesity) as it may reduce the amount of vitamin D₃ you absorb.
- Thiazide diuretics (medicines used to treat high blood pressure or oedema), as they may increase the amount of calcium in your blood.
- Roxadustat (a medicine used to treat anemia).

You should wait:

- 30 minutes to more than 2 hours between taking CALCEOS and bisphosphonates.
- More than 1 hour between taking CALCEOS and roxadustat
- More than 2 hours between taking Calceos 500mg/400IU Chewable Tablets and the following medicines: medicines containing strontium, iron or zinc, estramustine, thyroid hormones, some fluoroquinolones (ciprofloxacin, norfloxacin), tetracycline antibiotics.
- It is advisable to take Calceos 500mg/400IU Chewable Tablets at least 2 hours after or 6 hours before dolutegravir intake.

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

Possible interactions with food. You must take CALCEOS either before or after meals containing:

- oxalic acid (spinach, rhubarb, sorrel, cocoa, tea...),
- phosphate (pork meat, ham, sausages, processed cheese, dessert cream, drinks with cola...),
- phytic acid (complete cereals, dry vegetables, oleaginous seeds, chocolate...).

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Pregnancy, breast-feeding and fertility

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.

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.

Driving and using machines

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

Calceos 500mg/400IU Chewable Tablets contains sorbitol, sucrose and hydrogenated soya bean oil

Calceos 500mg/400IU Chewable Tablets contains 475mg sorbitol (E420) 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 contains sucrose (sucrose is present in small quantities in cholecalciferol concentrate). 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 contains hydrogenated soya bean oil. If you are allergic to peanut or soya, do not take this medicinal product (see Do not take CALCEOS 500mg/400IU Chewable Tablets).

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

Following symptoms may occur: loss of appetite, excessive thirst, feeling sick (nausea), vomiting, constipation, abdominal pain, muscle weakness, fatigue, mental health problems, increased urine output, bone pain, kidney stones and high blood pressure.

These symptoms may be part of milk-alkali which can occur when, for example, large amounts of calcium and carbonate containing drugs (so-called antacids) are taken at the same time (see "warnings and precautions").

In these cases, stop taking CALCEOS and immediately contact your doctor for action (who will undertake the necessary procedures).

If you take too many CALCEOS during a long time, calcium deposits may appear in blood vessels or body tissues.

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 (may affect up to 1 in 100 people):

- excess calcium levels in the blood or urine.

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

- constipation, flatulence, feeling sick (nausea), abdominal pain, diarrhoea.

- itching, skin rashes and hives (urticaria).

Not known (frequency cannot be estimated from the available data):

- Milk-alkali syndrome associated with a high concentration of calcium in the blood (hypercalcemia), elevated blood pH (alkalosis) and renal failure which may occur with large doses (see "Warnings and precautions" and "If you take more CALCEOS than you should").

- Serious allergic (hypersensitivity) reactions such as swelling of the face, lips, tongue or throat that may lead to difficulty breathing (angioedema or laryngeal oedema).

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 of the tablet are: xylitol, sorbitol, povidone, magnesium stearate, lemon flavouring (flavouring preparations, natural flavouring substances, maltodextrin, acacia, sodium citrate, citric acid, butylated hydroxyanisole), alpha tocopherol, hydrogenated soybean oil, gelatin, sucrose, silicon dioxide, corn starch.

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.

Distributed by:

Galen Limited, Seagoe Industrial Estate, Craigavon, BT63 5UA, UK.

Manufacturer:

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

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