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Package leaflet: Information for the user

CALCI-D 1000 mg/1000 IU chewable tablets

calcium / colecalciferol

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 have 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 2 weeks.

What is in this leaflet

1. What CALCI-D is and what it is used for
2. What you need to know before you take CALCI-D
3. How to take CALCI-D
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1. What CALCI-D is and what it is used for

CALCI-D chewable tablets contain two active substances, calcium carbonate and colecalciferol (vitamin D_3). Both calcium and vitamin D_3 are found in the diet and vitamin D is also produced in the skin after exposure to the sun.

CALCI-D is used:
- in the correction of calcium and vitamin D deficiencies in the elderly,
- in combination with osteoporosis treatments where calcium and vitamin D levels are too low or where there is a high risk of them being too low.

2. What you need to know before you take CALCI-D

Do not take CALCI-D:
- If you are allergic to calcium carbonate or colecalciferol (vitamin D_3) or any of the other ingredients of this medicine (listed in section 6);
- if you are inactive and have high levels of calcium in your blood (hypercalcaemia) or urine (hypercalciuria);
- if you have calcium deposits in the tissues of your body;
- if you have serious kidney problems;
- if you have kidney stones or calcium stones in general;
- if you have abnormally high levels of vitamin D;
- if you are less than 18 year of age.

Warnings and precautions
Talk to your doctor or pharmacist before taking CALCI-D.

Take special care with CALCI-D if you:
- if you have had kidney stones or otherkidney problems (your doctor will need to monitor your treatment carefully if your kidneys are not working properly to make sure you do not build up too much calcium in your blood)
- if you stay in bed for a long period (months) and if you have osteoporosis (brittle bones) because you may have high levels of calcium in your blood
- if you are taking any other products containing calcium or vitamin D. Additional doses of calcium and vitamin D should be taken under close medical supervision (your doctor or your pharmacist will be able to tell you if you do)
- if you have sarcoidosis (your doctor will be able to tell you if you do)
- if you experience symptoms similar to those of an overdose (see section 3) shortly after starting treatment, even though you are following the recommended dosage. In this case, talk to your doctor immediately, as this may be due to a previously undetected hereditary metabolic disease (idiopathic infantile hypercalcaemia). Early symptoms usually include loss of appetite, thirst, nausea, vomiting, constipation, abdominal pain, muscle weakness and fatigue. You may experience excessive urination which can lead to dehydration and excessive thirst (see section 3). If you experience any of these symptoms stop taking CALCI-D immediately and contact your doctor.

Other medicines and CALCI-D
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, especially:

Medicines that decrease the absorption or effect of CALCI-D:
- orlistat (a medicine used to treat obesity), bile acid sequestrants (used to treat high blood cholesterol levels, for example cholestyramine, colestipol), steroids (such as cortisone), mineral oils (such as paraffin oil used as a laxative or stool softener): these medicines may decrease the absorption of the vitamin D_3.
- phenytoin and barbiturates (for example phenobarbital), which are used to treat epilepsy: they may decrease the activity of vitamin D_3.
- some diuretics (water pills for example furosemide and ethacrynic acid), antacids (used for indigestion) that contain aluminium salts and thyroid hormones: these medicines can decrease the absorption of calcium and increase its elimination in the stools or urine.

Medicines that increase the absorption or effect of CALCI-D:
- some other diuretics (of the thiazide kind, for example hydrochlorothiazide) can decrease the elimination of calcium in the urine and thus cause too high calcium levels in the blood.
- antibiotic drugs, for example penicillin, neomycin and chloramphenicol can increase the absorption of calcium: your doctor may tell you to check your blood calcium during prolonged treatment with CALCI-D and any of these medicines.

Medicines whose absorption is decreased by CALCI-D :
- tetracycline antibiotics: when taking these leave at least three hours before taking CALCI-D . Do not take them at the same time.
- bisphosphonates (medicines used to treat or prevent osteoporosis) and sodium fluoride: when taking these leave at least three hours before taking CALCI-D.
- The efficacy of levothyroxine can be reduced by the concurrent use of calcium, due to decreased levothyroxine absorption. Administration of calcium and levothyroxine should be separated by at least four hours.
- The effect of quinolone antibiotics may be reduced if taken at the same time as calcium. Take quinolone antibiotics two hours before or six hours after taking CALCI-D.

Medicines whose effect is increased by CALCI-D:
- digitoxin (for example Lanoxin) or other cardiac glycosides used to treat heart disorders: calcium may increase their effect on the heart.

Tell your doctor and ask for advice before taking any other product containing vitamin D or its derivatives while taking CALCI-D.

CALCI-D with food and drink
Tell your doctor if you usually eat food that contains oxalic acid (e.g. spinach and rhubarb), phosphates (especially from food additives) or phytinic acid (whole cereals), since these may reduce the absorption of calcium contained in CALCI-D.

Tell your doctor and ask for advice before taking foodstuffs which may be fortified with vitamin D.

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.

CALCI-D chewable tablets should only be

used in pregnancy and breast-feeding when it has been recommended by a doctor.

Driving and using machines
CALCI-D has no influence on your ability to drive or use machines.

CALCI-D contains sucrose and isomalt (isomaltitol, E953)
This medicine contains sucrose and isomalt (isomaltitol , E953), if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take CALCI-D

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

The recommended dose:
Take 1 tablet of CALCI-D once a day, preferably during the evening meal.

Dosage in pregnant women: Please refer to section 2.

The tablets may be chewed or sucked, they must not be swallowed whole.
The tablet can be divided into equal doses.

If you take more CALCI-D than you should
Contact your doctor or go to the nearest hospital emergency department if you or someone near you has taken too much CALCI-D. Remember to take with you any remaining tablets and the box or this leaflet so that doctors know what has been taken.

The main consequence of an overdose is an increased calcium level in the blood and urine. The symptoms are not specific and may include nausea, vomiting, diarrhea, constipation, loss of appetite, weight loss, fatigue, muscle weakness, headache, thirst, dehydration, high blood pressure, drowsiness, dizziness, increased need to urinate, increased need to urinate at night, sweating, feeling of restlessness, irritability and fever. It is possible to form kidney stones and soft tissues calcification, which can lead to damage to the kidneys, blood vessels and heart. Severe intoxication can lead to an irregular heartbeat, while extremely high blood calcium levels can cause coma or even death.

In case of overdose, you should immediately stop taking CALCI-D and limit dietary calcium intake. Depending on the degree of hypercalcemia (increased calcium levels in the blood), your doctor will initiate further therapeutic measures (e.g., intravenous fluids and drugs such as corticosteroids or bisphosphonates).

If you forget to take CALCI-D
Take it as soon as you remember. Then take your next dose at the usual time. However, if it is almost time for your next dose, skip the missed dose and continue as usual. Never take two doses at the same time.

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

4. Possible side effects

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

The following effects are uncommon: (may affect up to 1 in 100 people)
- hypercalcaemia (too much calcium in your blood) - the symptoms include nausea, vomiting, lack of appetite, constipation, stomach ache, bone pain, extreme thirst, needing to pass urine more often, muscle weakness, drowsiness and confusion;
- hypercalciuria (too much calcium in your urine).

The following effects are rare: (may affect up to 1 in 1000 people)
- nausea;
- flatulence (dyspepsia);
- stomach ache;
- itching;
- constipation;
- rash;
- diarrhoea;
- hives.

The following effects are very rare: (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.

The following effects are not known (frequency cannot be estimated from the available data):
Serious allergic (hypersensitivity) reactions such as swelling of the face, lips or tongue, kidney stone, blood phosphate level above normal (hyperphosphatemia).

Reporting of side effects:
If you get any side effects, talk to your doctor or 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 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 CALCI-D

- Keep this medicine out of the sight and reach of children.
- Store below 25°C.
- Store in the original package in order to protect from light, and moisture.
- Stability has been demonstrated for 14 days after first opening the container.
- Do not use this medicine after the expiry date which is stated on the carton after EXP. 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 protect the environment.

6. Contents of the pack and other information

What CALCI-D contains
- The active substances are: calcium and colecalciferol (Vitamin D3).
  Each chewable tablet contains calcium 1000 mg (as calcium carbonate) and colecalciferol (Vitamin D3) 25 micrograms (equivalent to 1000 I.U).
- The other ingredients are: DL-alpha tocopherol (E307), medium chain triglycerides, modified food starch (E1450), sucrose, sodium ascorbate (E301), silicon dioxide (E551), povidone K29/32, isomalt (E953), sucralose, magnesium stearate, crospovidone and orange aroma.

What CALCI-D looks like and contents of the pack
CALCI-D chewable tablets are white to almost white round tablet with a break mark.

The tablets are packed in plastic tubes. Each plastic tube contains 14 tablets.

CALCI-D is available in pack sizes of 14 or 28 chewable tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:
Consilient Health Limited,
Floor 3, Block 3, Miesian Plaza,
Dublin 2, D02 Y754, Ireland

Manufacturer:
SMB Technology S.A.
Rue du Parc Industriel 39
B-6900 Marche-en-Famenne, Belgium

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