(NON-PRESCRIPTION) Package leaflet: Information for the user

Caltrate 600mg/400 IU, film-coated tablet
Calcium (as carbonate) and Cholecalciferol (Vitamin D_3)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

This medicine is available without prescription. However, you still need to take Caltrate, film-coated tablet carefully to get the best results from it. Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist 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 or pharmacist. 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.

What is in this leaflet

1. What Caltrate is and what it is used for

This medicine contains two active substances calcium and vitamin D_3. Calcium is an important constituent of bone and vitamin D_3 helps the absorption of calcium by the intestine and its deposition in the bones.

It is used:

- In the correction of calcium and vitamin D deficiencies in older people,
  - 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 Caltrate

Do not take Caltrate

- If you are allergic to calcium, vitamin D (cholecalciferol)or any of the other ingredients of Caltrate, in particular soya bean oil or peanut (listed in section 6).
- If you are suffering from kidney failure.
- If you have an abnormally high level of calcium in the blood (hypercalcaemia) and/or high levels of calcium in the urine (hypercalciuria), have calcium deposits in the kidneys (nephrocalcinosis), have kidney stones (calcium lithiasis) or are on a low-phosphate diet (food low in phosphorus).
- If you have high levels of vitamin D in your blood (hypervitaminosis D).

Warnings and precautions

Talk to your doctor or pharmacist before taking Caltrate

- In the case of long-term treatment with Caltrate, the quantity of calcium in the blood (calcaemia) must be regularly monitored. This monitoring is particularly important in older people and where treatment is being taken at the same time as cardiac glycosides (e.g. Digoxin) or diuretics (water tablets). Depending upon the result, your doctor may decide to reduce or even stop your treatment.

- You should take the tablet with a large glass of water (200 ml). If you are more than 65 years-old or have difficulties to swallow, you should divide the breakable tablet in two parts and take them with a large glass of water (200 ml).

Before taking Caltrate tell your doctor or pharmacist:

- If you have any kidney problems. You may need to limit the dose/amount or stop using Caltrate
- If you are suffering from an immune disorder (sarcoidosis) which may affect your liver, lungs, skin or lymph nodes as the amount of calcium in your blood and urine together with phosphate levels should be monitored.
- If you are immobile and are suffering from reduced bone mass (osteoporosis). This may increase the level of calcium in your blood too much which can cause side effects.
- If you are taking other medicines containing vitamin D_3 or calcium and any aluminium containing preparations. This may increase the level of calcium in your blood too much which can cause side effects.

Children and adolescents

Caltrate is not intended for use in children and adolescents.

Other medicines and Caltrate

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

- Keep 2-4 hours' time gap, before or after taking other drugs.
- If you are taking any other medicines together, as calcium may affect the absorption of other medicines. Always read the label of other medications before taking as some medications shouldn't be used along with calcium containing products.
- Thiazide diuretics (water tablets) , as they may reduce the amount of calcium excreted by your body and can increase blood calcium levels.
- Ion exchange resins such as cholestyramine or laxatives such as paraffin since these drugs may reduce the absorption of fat-soluble vitamins, e.g. vitamin D.
- Oral steroids, as they may reduce the amount of calcium in your blood.
- Orlistat (a medicine used to treat obesity), may disturb the absorption of fat-soluble vitamins, e.g. vitamin D.
- Phenytoin (a medicine for epilepsy) and barbiturates (medicines which help you sleep), as they may make the vitamin D_3 less effective.
- Cardiac glycosides (medicines used to treat heart problems), as they may cause more side effects if you take too much calcium.
- Tetracycline antibiotics, as the amount absorbed may be reduced.
- Estramustin (a medicine used in chemotherapy), thyroid hormones or medicines containing iron or zinc, as the amount absorbed may be reduced. Bisphosphonates (a treatment for bone conditions), fluoride or fluoroquinolones (a type of antibiotic), as the amount absorbed may be reduced.
- Other medicines containing calcium or vitamin D while you are taking Caltrate. This may increase the level of calcium in your blood.

Pregnancy and breast-feeding

Caltrate is not recommended for use during pregnancy. 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 any medicine.

Caltrate is not recommended for use during breast-feeding. Calcium and vitamin D_3 pass into breast milk.

Driving and using machines

No effects on the ability to drive and use machines are expected.

Caltrate contains sucrose, sodium and hydrogenated soya bean oil

Caltrate contains sucrose therefore if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Caltrate contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially sodium free.

Caltrate also contains partially hydrogenated soya bean oil therefore if you are allergic to peanut or soya, do not use this medicinal product.

3. How to take Caltrate

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

The recommended dose is 1 tablet twice a day for adults and older people (e.g. one in the morning and one in the evening).

You should take the tablet with a large glass of water (200 ml).

If you take more Caltrate than you should

If you have taken more Caltrate than you should **and** experience any of the symptoms of overdose, **stop taking** Caltrate and **immediately contact your doctor.** Symptoms of overdose may include: anorexia, excessive thirst, feeling sick (nausea), vomiting, constipation, abdominal pain, muscle weakness, fatigue, mental health problems, increased urine output, bone pain, kidney stones.

Excessive use of this product can lead to:

- hypervitaminosis (a condition of abnormally high storage levels of vitamins, which can lead to toxic symptoms)
- high blood calcium level, excessive urinary calcium excretion
- in the case of major overdosage, cardiac arrest may occur.

If you forget to take Caltrate

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

4. Possible side effects

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

Rare side effects (affects 1 to 10 users in 10,000): stomach pain/ache, diarrhoea, constipation, flatulence (wind), nausea (feeling sick), belching, vomiting, skin rash (rash), itchy skin (pruritus) and hives (urticaria).

Other side effects (frequency not known): allergic reactions such as swelling of the face, tongue or lips (angioedema).

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, website: www.hpra.ie

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

5. How to store Caltrate

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

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

Store below 25°C. Keep the bottle tightly closed in order to protect from moisture.

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 Caltrate contains

The active substances are:

Calcium (as carbonate) 600 mg
Cholecalciferol (Vitamin D_3) 400 IU

The other ingredients are: Tablet Core - microcrystalline cellulose, povidone, crospovidone type A, sodium laurilsulfate, sodium croscarmellose, magnesium stearate, DL-α-tocopherol, partially hydrogenated soya bean oil, bovine gelatin hydrolyzed, sucrose, corn starch, silicon dioxide. Tablet Coating - light liquid paraffin, talc OPADRY OY-S-27203 (methylhydroxypropylcellulose, titanium dioxide (E171), light liquid paraffin, sodium laurilsulfate, red iron oxide (E172), black iron oxide (E172), yellow iron oxide (E172)).

What Caltrate looks like and contents of the pack

Capsule-shaped grey/beige, film-coated tablets. One side is scored and engraved with “D” on the left and “600” on the right of the score. The other side is engraved with “Caltrate”.

20, 30, 60, 90 or 180 tablets in a bottle. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

GlaxoSmithKline Consumer Healthcare (Ireland) Limited
12 Riverwalk

Citywest Business Campus
Dublin 24,
Ireland.

Manufacturer:
Pfizer Consumer Manufacturing, Italy S.r.l., Via Nettunense 90, 04011 Aprilia (LT), Italy.

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National Requirements

France

Remove the navigation tools (pictograms from the PIL)

Ireland

Include the term ‘water tablets’ after diuretics