(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 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 excessive loss of calcium in the urine (hypercalciuria).
- If you have a condition that could lead to hypercalcaemia and/or hypercalciuria (e.g. overactive parathyroid glands, a disease of the bone marrow (myeloma), a malignant bone tumour (bone metastases).
- If you are suffering from kidney stones (calcium lithiasis) or have calcium deposits in your kidneys (nephrocalcinosis)

- If you are suffering from an excessive supply of vitamin D (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. 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 had kidney stones.
- If you are suffering from an immune disorder (sarcoidosis), as the amount of calcium in your blood and urine must be checked.
- 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. 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.

In particular,

- Thiazide diuretics (medicines used to treat high blood pressure), as they may increase the amount of calcium in your blood.
- Oral steroids, as they may reduce the amount of calcium in your blood.
- Orlistat (a medicine used to treat obesity), cholestyramine, laxatives such as paraffin oil, as they may reduce the amount of vitamin D_3 you absorb.
- 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. They should be taken at least **2 hours** before, or **4-6 hours** after Caltrate.
- Estramustin (a medicine used in chemotherapy), thyroid hormones or medicines containing iron, zinc or strontium, as the amount absorbed may be reduced. They should be taken at least **2 hours** before or after Caltrate.
- Bisphosphonates (a treatment for bone conditions), fluoride or fluoroquinolones (a type of antibiotic), as the amount absorbed may be reduced. They should be taken at least **3 hours** before or after Caltrate.

- Other medicines containing calcium or vitamin D while you are taking Caltrate. This may increase the level of calcium in your blood.

Caltrate with food and drink

In the two hours before taking Caltrate, you should avoid eating foods containing oxalic acid (e.g. spinach and rhubarb) or phytic acid (e.g. wholegrain cereals), which can reduce calcium absorption.

Pregnancy and breast-feeding

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.

This medicine may be used during pregnancy however the total daily intake of calcium should not be higher than 1500 mg and the daily intake of vitamin D not higher than 600 IU. Therefore, in the case of pregnancy, the daily dose of Caltrate must not exceed one tablet per day. Higher amounts may have a negative effect on the unborn child.

During breast-feeding you can use Caltrate. As calcium and vitamin D_3 passes into breast milk you have to check with your doctor first if your infant receives any other products containing vitamin D_3.

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). Pregnant women should only take 1 tablet per day.

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).
The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

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.

In the case of prolonged overdosage, calcium deposits may appear in blood vessels or body tissues.

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.

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

Rare side effects (affects 1 to 10 users in 10,000): constipation, flatulence, feeling sick (nausea), abdominal pain, diarrhoea, itching, skin rashes and urticaria.

Other side effects (frequency not known): kidney stones, vomiting *(usually a symptom of overdose),* allergic reactions including angioedema (sudden swelling of the face and neck with trouble breathing) and laryngeal oedema (throat swelling and tightness).

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, Earlsfort Terrace, IRL-Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; Email: medsafety@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

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- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

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