

This leaflet tells you about **CALTRATE® 600 + D** Tablets.

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

CALTRATE® 600 + D is available without a doctor's prescription, for your use as a nutritional supplement. Nevertheless, you still need to use **CALTRATE® 600 + D** carefully to get the best results from it.

Keep this leaflet. You may need to read it again.

Ask your doctor or pharmacist if you need more information or advice.

You must see a doctor if you experience troubling symptoms.

SCHEDULING STATUS:

No schedule.

PROPRIETARY NAME:

CALTRATE® 600 + D (Tablets)

1. WHAT CALTRATE® 600 + D CONTAINS:

CALTRATE® 600 + D contains two active substances, calcium and vitamin D.

Calcium is an important constituent of bone and vitamin D helps the absorption of the calcium by the intestine and its deposition in the bones.

The active substances are as follows:

Nutritional information per CALTRATE® 600 + D tablet	Each tablet contains	% NRV for adults and children 4 years and older**
Calcium*	600 mg	46,2 %
Vitamin D	400 IU	66,7 %

*1500 mg calcium carbonate equivalent to 600 mg elemental calcium.

**According to the nutrient reference values regulations published 1 March 2010

Nutritional information	Per 1 tablet dose
Energy	1,57 kJ
Protein	0 mg
Total Carbohydrate	94 mg
Sugars	86 mg
Dietary fibre	8 mg
Total fat	2 mg
Saturated fat	2 mg
Trans fat	0 mg
Sodium	0,454 mg

The complete list of ingredients is: Calcium carbonate, cholecalciferol (Vit. D₃), croscarmellose sodium, maltodextrin, Blue 2 Lake, Red 40 Lake, Yellow 6 Lake, medium-chain triglycerides, modified corn starch, magnesium stearate polyethylene glycol, polyvinyl alcohol, silicon dioxide, sodium ascorbate, sucrose, talc titanium dioxide and tocopherols

Contains no salt, lactose or preservatives
Gelatine free

Potential allergens: No known allergens

2. WHAT CALTRATE® 600 + D IS USED FOR:-

It is used:

- In the correction of calcium and vitamin D deficiencies.
- In the combination with osteoporosis treatments where calcium and vitamin D levels are low or where there is a high risk of them being too low.

3. BEFORE YOU TAKE CALTRATE® 600 + D:

Do not take CALTRATE® 600 + D:

If you are hypersensitive (allergic) to calcium, vitamin D or to one of the other ingredients of **CALTRATE® 600 + D**.

If you have an abnormally high level of calcium in the blood and /or excessive loss of calcium in the urine (hypercalciuria).

If you are suffering from kidney failure.

If you are suffering from kidney stones or have calcium deposits in your kidneys

If you are suffering from an excessive supply of vitamin D (hypervitaminosis D).

Take special care with CALTRATE® 600 + D:

If you are on long term treatment with **CALTRATE® 600 + D**, the quantity of calcium in the blood must be regularly monitored. This is particularly important in the elderly and where treatment is being taken at the same time as cardiac glycosides (e.g. digoxin) or diuretics (water tablets).

Consult a healthcare professional prior to use if:

- you have had kidney stones.
- you are suffering from an immune disorder (sarcoidosis), as the amount of calcium in your blood and urine must be checked.
- you are taking any other medicines containing vitamin D or calcium. This may increase the level of calcium in your blood too much which can cause side effects

Taking CALTRATE® 600 + D with food and drink:

In the two hours before taking **CALTRATE® 600 + D**, 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 breastfeeding:

If you are pregnant or breastfeeding, please consult your doctor, pharmacist or other healthcare professional for advice.

This medicine may be used during pregnancy, however the total daily intake of calcium should not be higher than 1 500 mg and the daily intake of vitamin D not higher than 600 IU.

During breastfeeding you can use CALTRATE[®] 600 + D. As calcium and vitamin D passes into breast milk, check with your doctor if your infant receives other products containing vitamin D.

Taking other medicines with CALTRATE[®] 600 + D:

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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.
- 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[®] 600 + D.
- 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[®] 600 + D.

Other medicines containing calcium or vitamin D while you are taking CALTRATE[®] 600 + D. this may increase the level of calcium in your blood.

4. HOW TO TAKE CALTRATE[®] 600 + D:

Always take CALTRATE[®] 600 + D as your doctor has told you. You should check with your doctor if you are not sure.

The usual dose is 1 tablet daily for adults and elderly.

You should take the tablet with a glass of water (200 ml). If you have difficulties in swallowing the tablet, you can halve the tablet.

Do not exceed the recommended dose.

If you take more CALTRATE[®] 600 + D than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you experience any of the symptoms of overdose, stop taking CALTRATE[®] 600 + D and immediately contact your doctor.

Symptoms of overdose may include: anorexia, excessive thirst, feeling sick (nausea), vomiting, constipation, abdominal pain, muscle weakness, fatigue, bone pain and kidney stones.

If you forget to take CALTRATE[®] 600 + D

Do not take a double dose to compensate for a forgotten tablet.

5. POSSIBLE SIDE EFFECTS:

CALTRATE[®] 600 + D can have side effects.

Not all side effects reported for **CALTRATE[®] 600 + D** are included in this leaflet.

Should your general health worsen while taking **CALTRATE[®] 600 + D** please consult your doctor, pharmacist or other healthcare professional for advice.

Tell your doctor if you notice any of the following:

Constipation, flatulence, feeling sick (nausea), abdominal pain, diarrhoea, itching, skin rashes and urticaria.

Other side effects: kidney stones.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF CALTRATE[®] 600 + D:

STORE AT OR BELOW 25 °C IN A DRY PLACE.

KEEP THE CONTAINER TIGHTLY CLOSED.

Keep out of reach and sight of children.

Do not store in a bathroom. Do not use after the expiry date stated on the label/carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF CALTRATE[®] 600 + D:

CALTRATE[®] 600 + D is packed in white plastic bottles and caps in counts of 30 or 60 tablets into a cardboard carton, with an insert.

This container is sealed with a tamper-evident foil for your safety.

Do not use if the foil is broken.

8. IDENTIFICATION OF CALTRATE[®] 600 + D:

CALTRATE[®] 600 + D is a rose coloured, oval shaped, film coated tablet, engraved with “600” on the left and “D” on the right of the bisect line and “Caltrate” on the opposite side.

9. NAME AND ADDRESS OF REGISTRATION HOLDER:

Pfizer Laboratories (Pty) Ltd
Co. Reg. No. 1954/000781/07
85 Bute Lane
Sandton
2196
South Africa

For more health benefits, visit www.caltrate.co.za