

This leaflet tells you about **CALTRATE® PLUS Tablets**.

Read all of this leaflet carefully because it contains important information for you. **CALTRATE® PLUS Tablets** is available without a doctor's prescription, for your use as a nutritional supplement. Nevertheless, you still need to use **CALTRATE® PLUS Tablets** 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.

PROPRIETARY NAME:

CALTRATE® PLUS Tablets

1. WHAT CALTRATE® PLUS Tablets CONTAINS:

The active substances are as follows:

Nutritional information per CALTRATE® PLUS Tablet	Each tablet contains	% NRV for adults and children 4 years and older**
Calcium*	600 mg	46,2 %
Vitamin D	500 IU	83,3 %
Magnesium	40 mg	9,5 %
Zinc	7,5 mg	68,2 %
Copper	0,5 mg	55,6 %
Manganese	1,8 mg	78,3 %

*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	1,78 kJ
Protein	0,0 mg
Total Carbohydrate	63,0 mg
Dietary fibre	227,0 mg
Total fat	4,0 mg
Saturated fat	3,0 mg
Sodium	3,0 mg

The complete list of ingredients is: Calcium carbonate, maltodextrin, tocopherols, vitamin D3, modified food starch, medium chain triglycerides, sodium ascorbate, sucrose, silicon dioxide, zinc oxide, cupric sulphate, magnesium oxide, manganese sulphate, croscarmellose sodium, microcrystalline cellulose, magnesium stearate, talc, light liquid paraffin, hydroxypropylmethylcellulose, titanium dioxide, sodium lauryl sulphate, FD&C red #40, FD&C yellow #6, FD&C Blue #1 and purified water.

Contains no lactose or preservatives

Gelatine free

2. WHAT IS CALTRATE® PLUS Tablets USED FOR:

CALTRATE® PLUS Tablets is a combined preparation with calcium for bone strength, vitamin D for calcium absorption and other important minerals for correction of calcium deficiencies, increase of bone density, prevention of bone mass reduction, and the support of collagen formation for flexibility and resilience of bones.

Healthy bone is made up of 2/3 calcium, and 1/3 collagen. The combination of collagen and calcium makes bone strong and flexible – more able to absorb impact.

It may be used on doctor's recommendation for supplementation of calcium and vitamin D during treatment of osteoporosis.

CALTRATE® PLUS Tablets is suitable as a supplement to be used during hormone replacement therapy in menopause, as recommended by a doctor.

Calcium:

is the most important component of bone tissue, and needed for bone turn-over throughout life. It is essential for maintenance of healthy and strong bones.

Vitamin D:

is required for proper absorption and storage of calcium in bones.

Magnesium:

is essential for metabolism of vitamin D and for bone function, helping to maintain bone strength.

Zinc:

is essential for the formation of protein and collagen. Up to 30 % of the body's supply of zinc is held in the skeletal tissue.

Copper:

is a cofactor for several enzymatic reactions, including that responsible for formation of collagen, a component of bone tissue.

Manganese:

plays an important role for formation of bones and cartilages, and is an enzyme co-factor for collagen formation.

3. BEFORE YOU TAKE CALTRATE® PLUS Tablets:

Do not take CALTRATE® PLUS Tablets:

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

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).

If your parathyroid glands have increased function.

If you suffer from sarcoidosis (an immune disorder).

Take special care with CALTRATE® PLUS Tablets:

If you are on long term treatment with **CALTRATE® PLUS Tablets**, 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 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® PLUS Tablets with food and drink:

In the two hours before taking **CALTRATE® PLUS Tablets**, 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.

CALTRATE® PLUS Tablets can be used during pregnancy and lactation.

During pregnancy 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.

As calcium and vitamin D passes into breast milk you have to check with your doctor first if your infant receives any other products containing vitamin D.

Taking other medicines with CALTRATE® PLUS Tablets:

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® PLUS Tablets**.
- 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® PLUS Tablets**.
- Other medicines containing calcium or vitamin D while you are taking **CALTRATE® PLUS Tablets** as this may increase the level of calcium in your blood.

4. HOW TO TAKE CALTRATE® PLUS Tablets:

Always take **CALTRATE® PLUS Tablets** 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. If you have difficulties in swallowing, you should divide the breakable tablets in two parts and take them with a large glass of water (approximately 200 ml).

Do not exceed the recommended dose.

If you take more CALTRATE® PLUS Tablets 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® PLUS Tablets** 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® PLUS Tablets

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

5. POSSIBLE SIDE EFFECTS:

CALTRATE® PLUS Tablets can have side effects.

Not all side effects reported for **CALTRATE® PLUS Tablets** are included in this leaflet.

Should your general health worsen while taking **CALTRATE® PLUS Tablets** 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.

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

6. STORING AND DISPOSING OF CALTRATE® PLUS Tablets:

STORE AT OR BELOW 25 °C IN A COOL 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® PLUS Tablets:

CALTRATE® PLUS Tablets are packed in white plastic bottles and caps in counts of 30, 60 or 90 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® PLUS Tablets:

CALTRATE® PLUS Tablet is a capsule shaped, dusty rose coloured film coated tablet, engraved “+” on left side and “P4” on the right side of the bisect on the scored side and engraved “CALTRATE” on the unscored 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