

This leaflet tells you about **CALTRATE® PLUS Chewables**

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

**CALTRATE® PLUS** is available without a doctor's prescription, for your use as a nutritional supplement. Nevertheless, you still need to use **CALTRATE® PLUS** 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® PLUS (Chewables)**

**1. WHAT CALTRATE® PLUS CONTAINS:**

The active substances are as follows:

<b>Nutritional information per CALTRATE® PLUS tablet</b>	<b>Each tablet contains</b>	<b>% NRV for adults and children 4 years and older**</b>
Calcium*	600 mg	46,2 %
Vitamin D	500 IU	83,3 %
Magnesium	40 mg	9,5 %
Zinc	7,5 mg	68,2 %
Copper	0,25 mg	27,8 %
Manganese	1,8 mg	78,3 %
Boron	70 µg	***

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

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

\*\*\* NRV not established

<b>Nutritional information</b>	<b>Per 1 tablet dose</b>
Energy	16 kJ
Protein	0 g
Total Carbohydrate	0,875 g
Dietary fibre	0,1705 g
Sugars	0,005 g
Sugar alcohols*	0,7022 g
Total fat	0,039 g
Saturated fat	0,0394 g
Trans fat	0 mg
Sodium	<1,295 mg

\*Amount calculated base on contribution from xylitol, polydextrose and sucralose.

The complete list of ingredients is: Calcium carbonate, xylitol, maltodextrin, magnesium oxide, acacia, cholecalciferol (Vit. D<sub>3</sub>), citric acid, corn syrup solids, cupric sulphate, dried cane syrup, hydrogenated palm oil, magnesium borate, magnesium stearate, manganese sulphate, medium chain triglycerides, modified food starch, natural and artificial flavours, polydextrose, silicone dioxide sodium ascorbate sucralose, sucrose, tocopherols, zinc oxide and colourants, blue 2 lake, red 40 lake and yellow 40 lake

Contains no salt, lactose or preservatives  
Gelatine free

Potential allergens: sulphites at a concentration of not more than 10 ppm

## **2. WHAT CALTRATE® PLUS IS USED FOR:**

**CALTRATE® PLUS** 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.

**CALTRATE® PLUS** is suitable as a supplement to be used during hormone replacement therapy in menopause.

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. It also helps in wound healing and supports proper function of nerves and muscles.

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.

Manganese:

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

Copper:

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

**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.

**Boron:**

assists in regulating calcium absorption.

**3. BEFORE YOU TAKE CALTRATE® PLUS:**

**Do not take CALTRATE® PLUS:**

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

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:**

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

In the two hours before taking **CALTRATE® PLUS**, 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** 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<sup>®</sup> PLUS:**

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

### **4. HOW TO TAKE CALTRATE<sup>®</sup> PLUS:**

Always take **CALTRATE<sup>®</sup> PLUS** 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. Chew the tablet completely before swallowing.

Do not exceed the recommended dose.

#### **If you take more CALTRATE<sup>®</sup> PLUS than you should:**

In the event of overdose, 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<sup>®</sup> PLUS** 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<sup>®</sup> PLUS**

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

### **5. POSSIBLE SIDE EFFECTS:**

**CALTRATE<sup>®</sup> PLUS** can have side effects.

Not all side effects reported for **CALTRATE<sup>®</sup> PLUS** are included in this leaflet.

Should your general health worsen while taking **CALTRATE<sup>®</sup> PLUS** 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<sup>®</sup> PLUS:**

**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<sup>®</sup> PLUS:**

**CALTRATE<sup>®</sup> PLUS** 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<sup>®</sup> PLUS:**

**CALTRATE<sup>®</sup> PLUS** chewable tablets have 3 assorted flavours.

Orange flavour – Orange round shaped tablets.

Cherry flavour – Red round shaped tablets.

Fruit punch flavour – Purple round shaped tablets.

All of the tablets are embossed with “Caltrate” over “PLUS” on one side and the other side “1”.

## **9. NAME AND ADDRESS OF REGISTRATION HOLDER:**

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