

Patient Information Leaflet

(OSTOCALCIUM PLUS CHEWABLE TABLETS)

Calcium (as Tribasic Calcium Phosphate) 250 mg and Cholecalciferol (Vitamin D₃) 400 IU

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

What is in this leaflet:

1. What *Ostocalcium Plus Tablets* are and what are they used for
2. What you need to know before you take *Ostocalcium Plus Tablets*
3. How to take *Ostocalcium Plus Tablets*
4. Possible side effects
5. How to store/handle *Ostocalcium Plus Tablets*
6. Contents of the pack and other information

1. What Ostocalcium Plus Tablets are and what are they used for

This medicine contains two active substances calcium and vitamin D₃. Calcium is an important constituent of bone and vitamin D₃ 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 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 Ostocalcium Plus Tablets

Do not take *Ostocalcium Plus Tablets*

- If you are allergic to calcium, vitamin D or any of the other ingredients of *Ostocalcium Plus Tablets*.
- 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 (nephrolithiasis) or have calcium deposits in your kidneys (nephrocalcinosis).

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

Warnings and precautions

Talk to your doctor before taking *Ostocalcium Plus Tablets*:

- In the case of long-term treatment with *Ostocalcium Plus Tablets*, 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.

Before taking *Ostocalcium Plus Tablets* tell your doctor:

- 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 D₃ or calcium. This may increase the level of calcium in your blood too much which can cause side effects.

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

- Phenytoin (a medicine for epilepsy) and barbiturates (medicines which help you sleep), as they make Vitamin D₃ less effective.
- 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 D₃ you absorb.
- Tetracycline antibiotics, as the amount absorbed may be reduced. They should be taken at least two hours before, or four to six hours after *Ostocalcium Plus Tablets*.
- Quinolones (a type of antibiotic), as the amount absorbed may be reduced. They should be taken at least two hours before, or four to six hours after *Ostocalcium Plus Tablets*.
- Cardiac glycosides (medicines used to treat heart problems), as they may cause more side effects if you take too much calcium.
- Bisphosphonates (a treatment for bone conditions), as the amount absorbed may be reduced. They should be taken at least 1 hour before taking *Ostocalcium Plus Tablets*.
- Calcium may also reduce absorption of sodium fluoride and such preparations should be administered at least three hours before taking *Ostocalcium Plus Tablets*.
- In the two hours before taking *Ostocalcium 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.

- Thyroid hormones, as the amount absorbed may be reduced. They should be taken at least 2 hours before or after *Ostocalcium Plus Tablets*.
- Medicines containing iron, zinc or strontium, as the amount absorbed may be reduced. They should be taken at least 2 hours before or after *Ostocalcium Plus Tablets*.

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 for advice before taking any medicine.
- As calcium and vitamin D₃ passes into breast milk you have to check with your doctor first if your infant receives any other products containing vitamin D₃.

Driving and using machines

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

3. How to take Ostocalcium Plus Chewable Tablets

- Ostocalcium Plus tablets are to be chewed before swallowing
- The daily dose is 2 tablets (equivalent to 500 mg of calcium and 800 IU of vitamin D) for adults and older people divided into 1 or 2 doses.
- The daily dose for children is 1 tablet daily (equivalent to 250 mg of calcium and 400 IU of vitamin D).
- If you take **more Ostocalcium Plus Tablets** than you should and experience any of the symptoms of overdose, stop taking ***Ostocalcium 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, 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.

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, diarrhea, 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 edema (throat swelling and tightness).

5. How to store/handle Ostocalcium Plus Tablets

- Store protected from light and moisture, at a temperature not exceeding 30°C.
- Keep out of reach of children.
- There are no other special requirements for use or handling of this product.
- Shelf life of the product is 18 months. Please see the Expiry Date as mentioned on the label & packaging

6. Contents of the pack and other information

- Each uncoated chewable tablet contains:
Cholecalciferol Concentrate (Powder Form) IP

equivalent to Cholecalciferol (Vitamin D3) 400 IU

Tribasic Calcium Phosphate IP 0.646 g

equivalent to 250 mg of elemental Calcium

(Appropriate overages added for Vitamin D3)

Color: Sunset Yellow FCF

The other ingredients are: Sucrose, Methyl Hydroxybenzoate, Propyl Hydroxybenzoate, Liquid Glucose S02 Free, Acacia Powder, Citric Acid Monohydrate, Magnesium Stearate, Colloidal Silicone Dioxide, Flavour Fruit DC/DCS 130 PH (Dry Mix), Purified Water.

- Tablets in an amber glass bottle.

- DETAILS OF MANUFACTURER:

Acme Generics Private Limited
Plot No. 115, HPSIDC, Industrial Area,
Vill. Davni, P.O. Gurumajra, Tehsil
Nalagarh, Distt. Solan (H.P.) – 174101, India

- MARKETED BY:

GlaxoSmithKline Asia Pvt. Ltd.
Patiala Road, Nabha – 147201, Punjab, India

- DETAILS OF PERMISSION OR LICENSE NUMBER

Manufacturing License Number: MB/15/881

- DATE OF REVISION

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- CONSUMER CARE DETAILS

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