



# CHOLECALCIFEROL + CALCIUM

## CALTRADIN

400 IU / 600 mg Film-Coated Tablet  
VITAMIN AND MINERAL

### PATIENT INFORMATION LEAFLET:

#### Formulation:

Each film-coated tablet contains:

Vitamin D<sub>3</sub>, USP ..... 10.00 mcg  
(equiv. to 400 IU Vit. D)  
Calcium Carbonate ..... 1500 mg  
(equiv. to 600mg elemental calcium)

#### Name of the Product

Cholecalciferol 10 mcg (equiv. to 400 IU Vit. D) + Calcium Carbonate 1500 mg (equiv. to 600 mg Calcium) (Caltradin) Film-Coated Tablet

#### Description of the Product

Vitamin D + Calcium 400 IU / 600 mg Film-Coated Tablet appears as pink, oblong, biconvex, film-coated tablet, bisected on one side and plain on the other side.

#### What is in the medicine?

Each film-coated tablet contains 400 IU of Vitamin D and 600 mg of Calcium as the active ingredients.

Other ingredients: Hydroxypropylmethylcellulose, Purified Water, Propylene Glycol, Microcrystalline Cellulose, Sodium Starch Glycolate, Sodium Lauryl Sulfate, and Magnesium Stearate.

Coating Materials: Hypromellose USP, Titanium Dioxide, FD & C Red #40, Purified Water, Ethyl Alcohol, and Methylene Chloride.

#### Strength of the medicine

400 IU / 600 mg Film-Coated Tablet

#### What is this medicine used for?

It is used for prevention and treatment of osteoporosis.

#### How much and how often should you use this medicine?

Adult - Take one tablet twice a day with food or as prescribed by the physician.

#### When should you not take this medicine?

- If you are allergic to calcium, vitamin D, or any other components of the product.
- If you have an abnormally high level of calcium in the blood (hypercalcemia) and / or hypercalciuria (e.g. overactive parathyroid glands, a disease of the bone marrow (myeloma), a malignant bone tumor (bone metastasis).
- 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).

#### Care that should be taken when taking this medicine?

- In the case of long-term treatment with vitamin D + calcium, the quantity of calcium in the blood must be regularly monitored. This monitoring is particularly important in the elderly and where treatment is being taken at the same time as cardiac glycosides or diuretics. Depending on 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 the tablet with a large glass of water (200 mL).

270mmx100mm

#### Undesirable Effects

The following may be associated with the use of vitamin D/calcium: Abdominal distension, abdominal pain, constipation, diarrhea, eructation/burping, flatulence, nausea, vomiting, high level of calcium in blood (hypercalcemia), excessive loss of calcium in urine (hypercalciuria) and kidney stone formation (nephrolithiasis).

#### What other medicine or food should be avoided while taking this medicine?

- Make sure your doctor knows if you are also using other supplements or medicines that contain calcium. Calcium can change the way other medicines work if you take them at the same time. If you need to use other medicines, take them at least 2 hours before or 2 hours after you take your calcium supplement. This is particularly important if you are also using phenytoin or tetracycline antibiotic to treat an infection (such as doxycycline, minocycline), fluoroquinolone antibiotics, and levothyroxine (thyroid medication).
- Do not take your calcium supplement with a high-fiber meal (such as bran, whole-grain cereal or bread, fresh fruits).
- Do not smoke cigarettes or cigars and do not drink large amounts of alcohol or caffeine ( for example, more than about 8 cups of coffee).

#### What should you do if you miss a dose?

Take the missed dose as soon as you remember. Skip the missed dose if it is almost time for your next schedule dose. Do not take extra medicine to make up the missed dose.

#### Signs and symptoms of overdose

Symptoms of overdose may include: constipation, nausea, vomiting, alkalosis, anorexia, milk-alkali syndrome, hypercalcemia, nephrolithiasis, and low level of phosphorus in the blood (hypophosphatemia).

#### What to do when you have taken more than the recommended dosage?

In case of accidental overdose, discontinue use and seek professional assistance immediately.

#### How should you keep this medicine?

Store at temperatures not exceeding 30°C.  
Keep out of reach of children.

#### When should you consult your Doctor?

When you take more vitamin D + calcium than you should, talk to a doctor.  
If you get any side effects, talk to your doctor.

#### Availability

Aluminum foil strip x 10's (Box of 100's)

#### ADR Reporting Statement

***"For suspected adverse drug reaction, report to the FDA:***

***[www.fda.gov.ph](http://www.fda.gov.ph)***

***Patients should seek medical attention immediately at the first sign of any adverse drug reaction."***

#### Registration Number

DRP-8071-01

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