# RASOCAL TABLET

## **Composition**:

Each film coated tablet contains:

Calcium Carbonate I.P. 1250mg. Eq. to El. Calcium 500mg. Cholecalciferol (Vit. D3) I.P. 250 I.U.

## **DESCRIPTION**

Calcium carbonate is a calcium supplement that is used in deficiency states and as an adjunct in the prevention and treatment of osteoporosis. Vitamin D3 is a fat-soluble sterol, it aids in the regulation of calcium and phosphate homeostasis and bone mineralization.

## **CALCIUM CARBONATE:**

Calcium carbonate is a chemical compound. It's most common natural forms are chalk, limestone, and marble, produced by the sedimentation of the shells of small fossilized snails, shellfish and coral over millions of years. It is commonly used medicinally as a calcium supplement or as an antacid, but excessive consumption can be hazardous. Calcium carbonate is a calcium supplement that is used in deficiency states and as an adjunct in the prevention and treatment of osteoporosis. It is essential component and participant in physiologic systems and reactions.

## PHARMACOLOGY:

Calcium is involved substantially in the formation of the bones, the teeth, the nerves, the muscles, and the blood coagulation. 99% of the total body calcium is found in the bones. In the body, parathyroid hormones, vitamin D (calcitriol) and calcitonin are responsible for the maintenance of the calcium homeostasis. Calcium can stimulate gastric acid secretion, corticosteroid and insulin production. The chemical formula of Calcium Carbonate is **CaCO3.** 

## **Pharmacokinetics:**

<u>Absorption</u>: Calcium carbonates get absorbed about 15 - 25% in the GI tract and convert to calcium chloride by gastric acid.

**Bioavailability**: All calcium salts bio-availability range from 23 - 37%.

<u>Metabolism</u>: Calcium carbonate is metabolite partially in liver through CYP450, though the exact metabolism process is still unknown.

**Excretion:** Calcium carbonate is mostly (80%) excreted through feces and partially (20%) urine.

**Half Life:** The exact half-life of Calcium carbonate is unknown.

## VITAMIN D3

Vitamin D is a group of fat-soluble secosteroids. Vitamin D3 is a fat-soluble sterol, it aids in the regulation of calcium and phosphate homeostasis and bone mineralization. When we expose in the sun our skin can synthesis enough Vit. D. In humans, vitamin D is unique because it can be ingested as cholecalciferol (vitamin D3) or ergocalciferol (vitamin D2).

Vitamin D is converted to calcidiol (25-hydroxyvitamin D or 25(OH) D) in the liver. Part of the calcidiol is converted by the kidneys to calcitriol (1, 25-(OH) 2D3 or 1,25- hydroxy vitamin D3), the biologically active form of vitamin D. This circulates as a hormone in the blood and regulates the concentration of calcium and phosphate in the bloodstream and promotes the healthy growth and remodeling of bone. Calcidiol is also converted to calcitriol outside of the kidneys for other purposes, such as the proliferation, differentiation and apoptosis of cells; calcitriol also affects neuromuscular function and inflammation. The chemical formula is  $C_{24}H_{44}O$ .

## Pharmacology:

Vitamin D is a fat-soluble vitamin that acts as a steroid hormone. The body makes vitamin D from cholesterol through a process triggered by the action of the sun's ultraviolet B rays on the skin. Factors such as skin color, age, amount and time of sun exposure, and geographic location affect how much vitamin D the body makes. Vitamin D influences the bones, intestines, immune and cardiovascular systems, pancreas, muscles, brain, and the control of cell cycles. Its primary functions are to maintain normal blood concentrations of calcium and phosphorus and to support bone health.

## **Pharmacokinetics:**

**Absorption**: Vitamin D3 is well-absorbed in the GI tract in presence of bile.

<u>Metabolism</u>: Vitamin D3 Undergoes hydroxylation in the liver and kidney to form the active metabolite, 1,25-dihydrocholecalciferol.

**Excretion**: Vitamin D and metabolites are mainly excreted in the bile and faeces.

#### **USES OF COMBINATION:**

This combination medication is used to prevent or treat low blood calcium levels in people who do not get enough calcium from their diets. It may be used to treat conditions caused by low calcium levels such as bone loss (osteoporosis), weak bones (osteomalacia/rickets), hypoparathyroidism, and a certain muscle disease like latent tetany. It may also be used in certain patients to make sure they are getting enough calcium like women who are pregnant, nursing or postmenopausal, people taking certain medications such as phenytoin, phenobarbital or prednisone.

Calcium plays a very important role in the body. It is necessary for normal functioning of nerves, cells, muscle, and bone. If there is not enough calcium in the blood, then the body will extract calcium from bones, thereby weakening bones.

Vitamin D helps our body to absorb calcium and phosphorus. Having the right amounts of vitamin D, calcium and phosphorus is important for building and keeping strong bones.

#### **HOW TO TAKE:**

Rasocal Tablet should take with food or take as directed by your doctor. For best absorption, if the total daily dose is more than 600 milligrams, then divide the dose and space it throughout the day. To get maximum benefit from Rasocal Tablet doctor may recommend to the patient to follow a special diet.

#### INDICATION:

Rasocal Tablet may be indicated in Fracture, Osteoporosis, Osteomalacia, Hypocalcemia and other degenerative bones disease.

### **CONTRAINDICATION:**

Patients with hypercalcaemia and / or hypercalciuria. Moreover Rasocal Tablet is contraindicated to the patients with Nephrolithiasis, hypervitaminosis D, hypophosphatemia.

## DOSAGE:

One tablet 2 or 3 time daily or as directed by the physicians.

### **SIDE EFFECTS**:

Constipation or stomach upset may occur. If any of these effects persist or worsen, then consult to the doctor or pharmacist immediately. Many people using this medication do not have serious side effects.

Seek medical attention immediately if serious side effects like nausea and vomiting, loss of appetite, unusual weight loss, mood changes, signs of kidney problems (such as change in the amount of urine), bone and muscle pain, headache, increased thirst, increased urination, weakness, tiredness, fast and pounding heartbeat. A serious allergic reaction to this drug is very rare. However, seek immediate medical attention if the symptoms of a serious allergic reaction like rash, itching and swelling, severe dizziness and trouble breathing.

### PRECAUTIONS:

<u>General</u>: Patients having allergic reaction to calcium carbonate or to other vitamin D products (such as calcitriol); or if the patient have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems.

This medication should not be used if the patient has certain medical conditions. Before using this medicine, consult to the doctor or pharmacist if the patient has high calcium or vitamin D levels or malabsorption syndrome.

Precaution must be taken to the patients suffering or have ever suffered kidney disease or stomach conditions.

## **Pregnant woman and breast feeding:**

Caution must be taken care of to the patients who are pregnant, plan to become pregnant. This medication passes into breast milk.

#### DRUG INTERACTION:

- 1. May affect the absorption of tetracycline when used together.
- 2. Corticosteroids may reduce calcium absorption.
- 3. Thiazide diuretics may decrease urinary excretion of calcium.
- 4. Hypercalcaemia may increase the toxicity of cardiac glycosides during treatment with calcium and vitamin D. So, regular ECG and serum calcium levels must be monitored.

#### FOOD INTERACTION:

Foods that are rich in oxalic acid and phytic acid may reduce calcium absorption. So, calcium products should not be taken within 2 hr of eating such foods.

#### STORAGE:

Store in cool and dry place in  $25 - 30^{\circ}$  Celsius.

### PRESENTATION:

Rasocal tablet is available 1\*15 in a blister strip and 10 strips in a carton.