

# RO-CAL CAPSULE

Calcitriol (0.25mcg)

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## What Ro-Cal is used for

Calcitriol is used to treat the following:

- Weaken bones (osteoporosis) in women after menopause.
- Bone disease (osteodystrophy) individuals with severe kidney failure and undergoing dialysis.
- Decreased function of the parathyroid gland (hypoparathyroidism)
- Softening in bones (rickets) due to vitamin-D resistant.
- Predialysis and dialysis individuals

## How Ro-Cal works

The sites of action of Calcitriol are intestine and bone. Calcitriol is an active form of vitamin D3. It helps to increase calcium absorption in the body.

## Before you use Ro-Cal

- When you must not use it

Do not take Ro-Cal if:

- You have any disease associated with an increase blood calcium level (hypercalcemia).
- You are allergic (hypersensitive) to calcitriol or any of the other ingredients.
- Vitamin D toxicity

If you are pregnant, trying to get pregnant or think you may be pregnant, consult your doctor before taking this medicine.

If you are breastfeeding, consult your doctor before taking this medicine.

- Before you start to use it

You must consult a doctor or pharmacist if you:

- You have high levels of calcium in your blood (Hypercalcemia).
- You have kidney failure.

- Taking other medicines

Consult a doctor or pharmacist if you are taking:

- Any other type of vitamin D.
- Extra calcium-containing medicine.
- Medicine like digitalis (used to treat heart disease).
- Corticosteroids
- Magnesium containing drugs (antacids).
- Phosphate-binding agents (e.g aluminium hydroxide for treatment of heartburn and gastritis).
- Enzyme inducers (phenytoin and phenobarbital).
- Colestyramine (to lower cholesterol).
- Ketoconazole (antifungal).

## How to use Ro-Cal

- How much to use

Follow all directions given in the insert carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Treatment should start at the lowest possible dose and should not increase without checking calcium level in the blood. While you are taking Ro-cal, your doctor will want you to have regular blood tests to check that the level of calcium in your blood does not get too high.

The dietary intake of calcium at the minimum of 600mg and not exceed 1000mg. Most people respond to between 0.5mcg and 1.0 mcg daily. Bone disease after menopause (Post-menopausal osteoporosis):

The usual dose is 0.25mcg twice a day.

Dialysis individuals:

The starting dose is 0.25mcg daily. The dose may be increase at 4 to 8 week intervals. Most individuals respond to doses between 0.5 to 1 mcg once a day.

Decreased function of the parathyroid gland (hypoparathyroidism):

The starting dose is 0.25mcg in the morning. The dose may be increase at 2 to 4 week intervals.

- When to use it

Use as directed in the leaflet.

- How long to use it

As per the dosage recommendation.

- If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor or pharmacist for advice immediately.

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Signs and symptoms included eating disorder, headache, vomiting, and constipation, degeneration of tissue, sensory disturbance, thirst, excessive or abnormally large production or passage of urine, dehydration, lack of interest, urinary tract infection and high level of calcium.

## While you are using it

### - Things you must do

Take your dose exactly as given in the leaflet.

Tell all the doctors, dentists and pharmacists that are treating you that you are taking Ro-Cal.

Consult a doctor immediately if you are become pregnant while taking this product.

### - Things you must not do

Do not give Ro-Cal to anyone else, even if they have the same symptoms or condition as you.

### - Things to be careful of *Driving and using machines*

This product does not affect your ability to drive or use machines.

Do not eat food which has vitamin D added (food which is 'fortified' with vitamin D) while you are taking Ro-cal.

## Side effects

Like all medicines, Calcitriol can cause side effects, although not everybody gets them.

The side effects are:

**Early:** Headache, weakness, Nausea or vomiting, constipation, abdominal pain, weight loss, drowsiness, dry mouth, muscle pain, bone pain, metallic taste, loss of appetite.

**Late:** inflammation of the eye, inflammation of the pancreas, runny nose, severe itching of

the skin, high level of body temperature, excess of cholesterol in the bloodstream, formation of crystals on the outer part of womb), deposition of calcium in the kidney, increased blood pressure, irregular heartbeat, inadequate nutrition, disorder of the senses and urinary tract infections.

**Rare:** personality disorders, itching of the skin, rash, skin rash with red, raised, itchy bumps and severe redness of the skin.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this Ro-Cal.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website [npra.moh.gov.my](http://npra.moh.gov.my) (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

## Storage and Disposal of Ro-Cal

### - Storage

Store below 30°C. Protect from light and moisture.

### - Disposal

Products should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## Product Description

### - What it looks like

Two pieces, white, size '2' hard vegetable capsules containing yellowish semisolid mass.

## - Ingredients

- Active ingredient(s)  
Calcitriol

- Inactive ingredients

Colloidal Silicon dioxide  
Vegetable oil  
Lauroyl polyoxyl-32 glycerides  
Medium Chain Triglycerides  
Butylated hydroxyl anisol  
Butylated hydroxyl toluene

## - MAL number(s):

Ro-Cal 0.25mcg Capsule:  
MAL10070596X

## Manufacturer

PAHANG PHARMACY  
SDN.BHD.  
Lot 5979, Jalan Teratai, 5 ½  
Miles Off, Jalan Meru,  
41050 Klang, Selangor Darul  
Ehsan.

## Product Registration Holder

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## Date of Revision

23/11/2017

## Serial Number

NPRA(R4/1)301017/00293