

PRODUCT MONOGRAPH

PrROCALTROL[®]

calcitriol

Capsules 0.25 µg and 0.5 µg

Vitamin D3 Metabolite

Hoffmann-La Roche Limited
7070 Mississauga Road
Mississauga, Ontario
L5N 5M8
www.rochecanada.com

Date of Revision:
January 25, 2016

Submission Control No: roc.25.jan.2016

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PART III: CONSUMER INFORMATION**Pr** **ROCALTROL**[®]
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This leaflet is part III of a three-part "Product Monograph" published for ROCALTROL and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about ROCALTROL. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION**What the medication is used for:**

ROCALTROL is indicated in the management of

- Calcium deficiency (hypocalcemia) and bone disease in patients with chronic renal failure undergoing dialysis
- Calcium deficiency (hypocalcemia) in patients with hypoparathyroidism (underactive parathyroid glands).
- Rickets (type of bone disease).

What it does:

ROCALTROL helps patients with kidney or bone disease (eg. rickets) who cannot make enough of the active form of vitamin D in the body to meet their needs. ROCALTROL supplies this form of vitamin D which the body can use to meet requirements.

When it should not be used:

- If you are allergic to the medicinal ingredient calcitriol, vitamin D, other vitamin D products or other forms of vitamin D or to any of the nonmedicinal ingredients in this formulation (see **What the non-medicinal ingredients are**).
- If you have hypercalcemia (high levels of calcium in the blood).

What the medicinal ingredient is:
calcitriol**What the important non-medicinal ingredients are:**

butylhydroxyanisole, butylhydroxytoluene, medium-chain triglycerides (fractionated coconut oil), gelatin, glycerol 85%, hydrogenated products of partially hydrolysed starch, red and yellow iron oxide E172, titanium dioxide E171.

What dosage forms it comes in:

Capsules 0.25 µg: brown-orange to red-orange, opaque (first-half)/white to grey-yellow or grey-orange, opaque (second half) oval soft gelatin capsules.

Capsules 0.50 µg: brown-orange to red-orange, opaque oval soft gelatin capsules.

WARNINGS AND PRECAUTIONS

BEFORE you use ROCALTROL talk to your doctor or pharmacist if:

- you are allergic to vitamin D or other forms of vitamin D products or to any ingredient of ROCALTROL.
- you have a history of kidney disease.

- you are undergoing dialysis.
- you have a history of heart disease.
- you are using cardiac glycosides (eg. digitalis).
- you are pregnant or planning to become pregnant during treatment.
- you are breastfeeding or planning to breastfeed. ROCALTROL may be released in human breast milk. Discuss with your doctor.
- you are taking any other drugs including non-prescription drugs, other vitamin D products, or other forms of vitamin D or any other vitamins or supplements.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with ROCALTROL include: digitalis, bile acid sequestrants (including cholestyramine and sevelamer) and mineral oil, anticonvulsants (e.g. phenytoin, phenobarbital), calcium supplements, corticosteroids, ketoconazole, magnesium-containing drugs (e.g. some antacids), thiazides.

PROPER USE OF THIS MEDICATION

The effectiveness of ROCALTROL therapy is based on the assumption that each patient is receiving an adequate daily intake of calcium.

To ensure that you receive an adequate daily intake of calcium, your doctor may either prescribe a calcium supplement or instruct appropriate dietary measures. Your doctor may monitor your blood levels of calcium and phosphorus.

Be sure to drink plenty of fluids to maintain good hydration, important during ROCALTROL treatment.

Usual adult dose:

Dosage is based on your medical condition and response to therapy. Your doctor may start you on a low dose and adjust the dose slowly to find the best dose for you. Follow your doctor's directions carefully.

Missed Dose

Take your missed dose as soon as you remember. Skip taking the missed dose if it is almost time for the next scheduled dose. No extra medicine should be taken to make up the missed dose.

Overdose:

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

The most common side effect of ROCALTROL is hypercalcemia -high calcium levels in the blood (see Serious Side Effects table below for symptoms). Common side effects include nausea, vomiting, stomach cramps, itching and sleeplessness.

Other side effects include agitation, sleeplessness, lack of feeling, weakness, constipation, upper abdominal pain, redness or itching

of the skin, excessive thirst, fever and joint pain. If these side effects become bothersome or persist, contact your doctor.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Very common	<p>Higher blood calcium levels than normal.</p> <p>Possible symptoms:</p> <p><i>Early symptoms:</i> weakness, headache, drowsiness, nausea, irregular heartbeat, excessive thirst, vomiting, dry mouth, constipation, muscle pain, bone pain, metallic taste, abdominal pain or stomach ache.</p> <p><i>Late symptoms:</i> frequent urination (including needing to urinate at night), excessive thirst, urinary tract infections, anorexia, weight loss, conjunctivitis, inflammation of the pancreas, sensitivity to light, runny nose, itching, feeling feverish, decreased sex drive, too much protein in the urine, high cholesterol, elevated liver function tests, excessive calcium in tissues, high blood pressure, irregular heartbeat, and rarely, loss of contact with reality.</p>		√	

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your
Common	Headache Abdominal pain - Rash Urinary tract infection		√	
Uncommon	Decreased appetite Vomiting		√	
Not known	<p>Allergic reactions - Possible symptoms: hives, difficulty breathing, swelling of your face, lips, tongue, or throat.</p> <p>Difficulty in understanding Growth retardation Excessive urination Calcium deposits on the skin Weight loss</p>		√	√

This is not a complete list of side effects. For any unexpected effects while taking, ROCALTROL contact your doctor or pharmacist.

HOW TO STORE IT

Capsules should be stored a 15-25°C. Store in the original container. Protect from light and moisture. Keep blister in the outer carton. Keep out of sight and reach of children.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: **Canada Vigilance Program**
Health Canada
Postal Locator 0701E
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at www.rochecanada.com or by contacting the sponsor Hoffmann-La Roche Limited at 1-888-762-4388.

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Last revised: January 25, 2016

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