

PART III: CONSUMER INFORMATION**PrRISEDRONATE**
Risedronate Sodium Tablets, USP
(as the hemi-pentahydrate)

This leaflet is part III of a three-part "Product Monograph" published when RISEDRONATE was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about RISEDRONATE. Contact your doctor or pharmacist if you have any questions about the drug.

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

- Treatment and prevention of osteoporosis in postmenopausal women.
- Treatment of osteoporosis in men, to improve bone mineral density.

What it does:

RISEDRONATE is a bisphosphonate drug that helps to slow bone loss. In many people, RISEDRONATE helps to increase bone density. In osteoporosis, the body removes more bone than it replaces. This causes bones to get weaker and more likely to break or fracture (usually at the spine, wrist or hip). Spine fractures may result in a curved back, height loss or back pain. RISEDRONATE corrects this imbalance by decreasing the elevated rate of bone removal. RISEDRONATE can therefore help reduce the risk of spine and non-spine fractures.

Since it is not known how long RISEDRONATE should be continued for patients with osteoporosis, you should discuss the need to stay on this medication with your doctor regularly to determine if RISEDRONATE is still right for you

Your doctor may measure the thickness (i.e., density) of your bone through a bone mineral density (BMD) test or x-ray to check your progress against further bone loss or fracture.

RISEDRONATE is not a pain reliever. Your doctor may prescribe or recommend another medicine specifically for pain relief.

When it should not be used:

- If you have low blood calcium levels (hypocalcemia).
- If you are allergic to risedronate sodium or any other ingredients in RISEDRONATE

What the medicinal ingredient is:

Risedronate sodium

What the non medicinal ingredients are:

35 mg: Colloidal Silicon Dioxide, Iron Oxide Yellow, Iron Oxide Red, Maltodextrin, Mannitol, Polyvinyl Alcohol, Polyethylene glycol/macrogol, Povidone, Pregelatinized Starch,

Sodium Starch Glycolate, Sodium Stearyl Fumarate, Talc, Titanium Dioxide.

What dosage forms it comes in:

Tablets: 35 mg

WARNINGS AND PRECAUTIONS

Before you use RISEDRONATE, talk to your doctor or pharmacist if:

- You have had problems or disease in your kidneys, esophagus (the tube connecting the mouth and the stomach), stomach or intestines.
- You cannot carry out dosing instructions (see PROPER USE OF THIS MEDICATION).
- You are pregnant or nursing.
- You have one of the following risk factors: cancer, chemotherapy, radiotherapy of the head or neck, treatment with corticosteroids, or dental problems or dental infections. If so, a dental examination and any necessary dental procedures should be considered before you start treatment with RISEDRONATE.

Calcium and vitamin D are also important for strong bones. Your doctor may ask you to take calcium and vitamin D while you are on RISEDRONATE therapy (see INTERACTIONS WITH THIS MEDICATION section).

INTERACTIONS WITH THIS MEDICATION

If taken with some other medicines, the effects of RISEDRONATE or the effects of other medicines may be changed. It is important to tell your healthcare providers, including doctors and dentists, about all medications you are taking, even if the medicine does not require a prescription (including vitamin and herbal supplements).

You should not take RISEDRONATE with food, as it may prevent your body from absorbing or using RISEDRONATE. You should take RISEDRONATE on an empty stomach. (See PROPER USE OF THIS MEDICATION for instructions)

Vitamins, mineral supplements, antacids and other medications may contain substances (e.g., calcium, magnesium, aluminum, and iron) which can stop your body from absorbing or using RISEDRONATE. These medications should be taken at a different time of day than RISEDRONATE.

PROPER USE OF THIS MEDICATION

As with all medications, it is important to take as directed by your doctor.

Usual dose:**Treatment of postmenopausal osteoporosis:**

- 1 tablet (35 mg) per week

Prevention of postmenopausal osteoporosis:

- 1 tablet (35 mg) per week

Treatment of Osteoporosis in Men, to Improve Bone Mineral Density:

- 1 tablet (35 mg) per week

DOSING INSTRUCTIONS

- Aside from plain water, do not eat or drink for at least 30 minutes after taking Risedronate.
- RISEDRONATE should be taken in the morning on an empty stomach at least 30 minutes before consuming the first food, drink (other than plain water) and/or any other medication of the day. Food, medication or drink other than plain water can interfere with the absorption of risedronate sodium.
- Each RISEDRONATE tablet should be swallowed whole while you are in an upright position and with sufficient plain water (≥ 120 mL or $\frac{1}{2}$ cup) to facilitate delivery to the stomach.
- You should not lie down for at least 30 minutes after taking the medication. You may sit, stand or do normal activities like read the newspaper, take a walk, etc.
- RISEDRONATE tablets should not be chewed, cut, or crushed.

These recommendations help RISEDRONATE work correctly and help you avoid possible irritation of the esophagus (the tube connecting the mouth and the stomach).

Clinical benefits may be compromised by failure to take RISEDRONATE on an empty stomach.**Once weekly dosing (35 mg per week):**

- Choose a day of the week to take your tablet.
- On your chosen day, take one RISEDRONATE tablet first thing in the morning with plain water before you have anything to eat or drink.

Missed Dose:

Weekly dose (35 mg tablet): If you forget to take your dose on the regularly scheduled day, simply take 1 tablet on the day you first remember having missed your dose. Then resume your schedule by taking 1 tablet on the originally chosen day of the week. If you've missed your dose by exactly one week, do not take 2 tablets on the same day. Simply take 1 tablet as you normally would have on this day and resume your usual weekly schedule.

Overdose:

If you take too many tablets on any given day, drink a full glass of milk and contact your health care practitioner, hospital emergency department or regional Poison Control Center immediately, even if there are no symptoms. Do not induce vomiting.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Drugs like RISEDRONATE may cause problems in your esophagus (the tube connecting the mouth and the stomach), stomach and intestines, including ulcers. If you have trouble or pain upon swallowing, heartburn, chest pain and black or bloody stools, stop taking RISEDRONATE and tell your doctor right away. Remember to take RISEDRONATE as directed.

In clinical studies of osteoporosis with risedronate sodium, the most commonly reported side effects were abdominal pain, heartburn and nausea.

RISEDRONATE may cause pain in bones, joints or muscles, rarely severe. Pain may start as soon as one day or up to several months after starting RISEDRONATE.

RISEDRONATE at monthly doses may cause short-lasting, mild flu-like symptoms. These symptoms usually decrease after subsequent doses.

Rarely patients have reported non-healing jaw wounds while receiving risedronate sodium or other drugs in this class. Consult your doctor if you experience persistent pain in your mouth, teeth or jaw, or if your gums or mouth heal poorly.

Very rarely patients have reported unusual fractures in their thigh bone while receiving drugs in this class. Consult your doctor if you experience new or unusual pain in your hip, groin, or thigh.

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 seek immediate emergency medical attention.
	Only if severe	In all cases	
Common (more than 1 in 100)			
Pain in bones, joints, or muscles	√		
Abdominal pain	√		
Uncommon (less than 1 in 100)			
Eye pain, redness or inflammation; sensitivity to light, decreased vision			√
Rare (less than 1 in 1,000)			
Painful tongue		√	
Jaw problems associated with delayed healing and infection, often following tooth extraction.		√	
Very rare (less than 1 in 10,000)			
Allergic reactions such as: hives; rash (with or without blisters); swelling of face, lips, tongue, or throat; difficult or painful swallowing; trouble breathing			√
Symptoms of low blood calcium level such as numbness, tingling, muscle spasms		√	
New or unusual pain in hip, groin or thigh		√	

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

HOW TO STORE IT

- Keep RISEDRONATE and all other medications out of the reach of children.
- Store between 15°C and 30°C.
- Do not keep medicine that is out of date or that you no longer need.

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, ON 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 obtained by contacting Pro Doc Ltée at 1-800-361-8559, www.prodoc.qc.ca or info@prodoc.qc.ca.

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