

PART III: CONSUMER INFORMATION

^{Pr} RISEDRONATE
Risedronate sodium (as monohydrate)

This leaflet is Part III of a three part “Product Monograph” published when RISEDRONATE was approved for sale in Canada. It 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
- Treatment and prevention of osteoporosis caused by treatment with steroid medication such as prednisone
- Treatment of Paget’s disease of bone

What it does:

RISEDRONATE is a biphosphonate drug that helps to slow bone loss. In many people, risedronate sodium helps to increase bone density. In osteoporosis, the body removes more bone than it replaces. This causes bones to get weaker and more likely 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 sodium 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 sodium 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:

Colloidal silicon dioxide, lactose monohydrate, magnesium stearate, pregelatinized starch, sodium stearyl fumarate, starch and film-coating containing the following:

5 mg: D&C yellow #10 lake, hydroxypropyl methylcellulose, iron oxide yellow, polyethylene glycol, polysorbate and titanium dioxide.

30 mg: hydroxypropyl methylcellulose, polyethylene glycol, polysorbate and titanium dioxide.

35 mg: FD&C yellow #6/sunset yellow FCF aluminium lake, hydroxypropyl methylcellulose, iron oxide red, iron oxide yellow, polyethylene glycol, polysorbate and titanium dioxide.

What dosage forms it comes in:

RISEDRONATE is available as tablets. Each tablet contains: risedronate sodium 5 mg (yellow), 30 mg (white), 35 mg (orange)

WARNINGS AND PRECAUTIONS

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

- have problems or disease in your kidneys, esophagus (the tube connecting the mouth and stomach), stomach or intestines.
- cannot carry out dosing instructions (see PROPER USE OF THIS MEDICATION).
- are pregnant or nursing.
- have one of the following risk factors: cancer, diabetes, chemotherapy, radiotherapy of the head or neck, immunosuppression, poor oral hygiene, treatment with corticosteroids or angiogenesis inhibitors (drugs that slow down the growth of new blood vessels and are used mostly to treat cancer)
- had or have pain, swelling or numbness of the jaw or loosening of a tooth or any other oral symptoms.

Your doctor should inspect your mouth and may ask that you have a dental examination prior to treatment with RISEDRONATE. Dental work should be done before you receive treatment with RISEDRONATE, and dental procedures should be avoided during treatment. It is important that you practice good dental hygiene, routine dental care and have regular dental check-ups while being treated with RISEDRONATE. Immediately report any oral symptoms such as loosening of a tooth, pain, swelling, or non-healing sores or discharge (pus or oozing) during your 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 health care 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).

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. Talk to your health care provider about how and when to take these medications.

Taking RISEDRONATE with corticosteroids or angiogenesis inhibitors may increase your chance of osteonecrosis of the jaw.

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 instruction).

If you are taking RISEDRONATE for Paget's disease, talk to your doctor before taking ASA or other non-steroidal anti-inflammatory drugs used for pain management because the risk of stomach upset may be increased.

PROPER USE OF THE MEDICATION

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

Usual Dose:

Treatment of postmenopausal osteoporosis:

- 1 tablet (5 mg) per day or
- 1 tablet (35 mg) per week or

Prevention of postmenopausal osteoporosis:

- 1 tablet (5 mg) per day or
- 1 tablet (35 mg) per week

Treatment of osteoporosis in men, to improve bone mineral density:

- 1 tablet (35 mg) per week

Treatment and prevention of glucocorticoid-induced osteoporosis:

- 1 tablet (5 mg) per day

Paget's disease of the bone:

- 1 tablet (30 mg) per day

DOSING INSTRUCTIONS

- 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.
- 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.
- Aside from plain water, do not eat or drink for at least 30 minutes after taking RISEDRONATE.
- 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).

Once daily dosing (5 or 30 mg per day):

- Take 1 RISEDRONATE tablet first thing in the morning with plain water before you have anything to eat or drink.

Once weekly dosing (35 mg per week):

- Choose a day of the week to take your tablet.
- On your chosen day, take 1 RISEDRONATE tablet first thing in the morning with plain water before you have anything to eat or drink.

Missed Dose:

Daily dose (5 mg or 30 mg tablet): If you forget to take your dose, do not double your next dose (i.e., do not take 2 tablets on the same day). Simply take 1 tablet at your next scheduled time.

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, contact your doctor, or a Poison Control Centre, or an emergency room of the nearest hospital immediately. Drink a full glass of milk. Do not induce vomiting.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Drugs like RISEDRONATE may cause problems in your esophagus (the tube that connects 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. In studies of Paget’s disease, diarrhea and headache were also commonly reported.

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.

IMPORTANT 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	
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		✓	
Osteonecrosis of the jaw:		✓	

Jaw problems associated with numbness or feeling of heaviness in the jaw, poor healing of the gums especially after dental work, loose teeth, exposed bone in the mouth, sores or non-healing sores in the mouth, discharge, dry mouth, swelling gum, infections, bad breath or pain in the mouth, teeth or jaw.			
Very rare (less than 1 in 10,000)			
Allergic and skin 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.
- Keep the tablets in their original package and store at controlled room temperature (15°C - 30°C). Protect from light.
- Do not keep medicine that is out of date or that you no longer need.

Reporting Side Effects

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:

- Online at MedEffect (<http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
 - Fax to 1-866-678-6789 (toll-free), or
 - Mail to: Canada Vigilance Program

Health Canada
Postal Locator 0701E
Ottawa, ON
K1A 0K9

Postage paid labels and the Consumer Side Effect Reporting Form are available at MedEffect (<http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php>).

NOTE: Contact your health professional if you need information about how to manage your side effects. 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 by contacting Sanis Health Inc., at:
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