

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrRISEDRONATE

risedronate sodium tablets

Read this carefully before you start taking **RISEDRONATE** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **RISEDRONATE**.

What is RISEDRONATE used for?

RISEDRONATE is used in adults to:

- treat or prevent osteoporosis in postmenopausal women
- increase bone density in men with osteoporosis.

How does RISEDRONATE work?

RISEDRONATE contains the medicinal ingredient risedronate sodium. Risedronate sodium belongs to a class of non-hormonal drugs called bisphosphonates. Bisphosphonates are similar to a molecule naturally made in your body that breaks down bone tissue. RISEDRONATE binds to the receptors in your body to prevent the bone from breaking down. This slows down bone loss which can help to reduce the risk of fractures. In many people RISEDRONATE helps to increase bone density.

What are the ingredients in RISEDRONATE?

Medicinal ingredients: risedronate sodium hemi-pentahydrate

Non-medicinal ingredients: crospovidone, ferric oxide yellow, ferric oxide red, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol and titanium dioxide.

RISEDRONATE comes in the following dosage forms:

Tablets. Each tablet contains risedronate sodium 35 mg.

Do not use RISEDRONATE if:

- You have low levels of calcium in your blood (hypocalcemia).
- You are allergic to risedronate sodium or any of the other ingredients RISEDRONATE (see **What are the ingredients in RISEDRONATE**).

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take RISEDRONATE. Talk about any health conditions or problems you may have, including if you:

- have or have had problems swallowing or have problems with your esophagus (the tube that connects your mouth to your stomach)
- have or have had stomach or digestive problems
- have or have had kidney problems
- cannot stand or sit upright for at least 30 minutes (see **How to take RISEDRONATE**)
- are pregnant or breastfeeding
- have one of the following risk factors for developing osteonecrosis (bone damage in the jaw):
 - have cancer and/or are currently receiving chemotherapy
 - are currently having or have had radiotherapy of the head or neck
 - have an infection or a lowered immune system (immunosuppression)
 - are taking corticosteroids (used to treat inflammation) or cancer drugs such as angiogenesis inhibitors (used to slow down the growth of new blood vessels)
 - have diabetes (high blood sugar)
 - have poor oral hygiene or dentures that do not fit well
 - have or have had pain, swelling or numbness of the jaw or loosening of a tooth
 - have sores in your mouth. Your healthcare professional may tell you not to take RISEDRONATE until all the sores in your mouth have healed.
 - are or have been a smoker
 - have or have had poor dental health, teeth or gum disease
 - have anemia (low red blood cell count)
 - have a blood disorder where your blood cannot form clots in the normal way
- are lactose intolerant or have one of the following rare hereditary diseases:
 - Galactose intolerance
 - Lapp lactase deficiency
 - Glucose-galactose malabsorption

Because lactose is a non-medicinal ingredient in the 35 mg RISEDRONATE tablets.

Other warnings you should know about:

Gastrointestinal Problems: Taking RISEDRONATE incorrectly may cause you to experience problems with your esophagus. Stop taking RISEDRONATE and talk to your healthcare professional if you experience difficulty or pain upon swallowing, chest/breastbone pain or new or worsening heartburn. To avoid problems with your esophagus and to allow the drug to reach the stomach, consider the following instructions:

- swallow each tablet of RISEDRONATE with a full glass of water.
- do NOT chew or suck the tablet.

- do NOT lie down for at least 30 minutes after taking RISEDRONATE or until you have had your first meal of the day.
- do NOT take RISEDRONATE at bedtime or before starting your day.

Eye Problems: Drugs like RISEDRONATE may cause vision problems. Different parts of your eye may experience inflammation or you may develop an eye infection. Your healthcare professional may end your treatment if they see symptoms of inflammation.

Oral Health: Your healthcare professional should check your mouth and may ask you to see your dentist before you start taking RISEDRONATE. Dental work should be done before you start treatment with RISEDRONATE. Tell your healthcare professional if you recently had any major dental procedures like an extraction or a root canal. Take good care of your teeth and gums and see the dentist for regular checkups while taking RISEDRONATE.

Calcium and Vitamin D: Calcium and vitamin D are also important for strong bones. Your healthcare professional may ask you to take calcium and vitamin D while you are on RISEDRONATE.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with RISEDRONATE:

- Vitamins, mineral supplements and antacids may contain substances that can stop your body from absorbing RISEDRONATE. They include calcium, magnesium, aluminum and iron. Take these medicines at a different time of day than RISEDRONATE. Talk to your healthcare professional about how and when to take these medications.
- Taking RISEDRONATE with corticosteroids or cancer drugs like angiogenesis inhibitors may increase your chance of jaw bone problems (osteonecrosis of the jaw).
- Talk to your healthcare professional before taking pain medication like ASA or other non-steroidal anti-inflammatory drugs (NSAIDs) because they may upset your stomach.

How to take RISEDRONATE:

- Take RISEDRONATE exactly as your healthcare professional tells you to.
- Take RISEDRONATE in the morning **on an empty stomach**, at least 30 minutes before you eat, drink or take other medicines.
- Swallow each RISEDRONATE tablet whole, while you are sitting or standing in an upright position. Drink enough **plain water** (at least 120 mL or ½ cup) to make sure the tablet gets to your stomach. Do not chew, cut or crush the tablets.
- Do not lie down for at least 30 minutes after taking RISEDRONATE.

Usual dose:***To treat osteoporosis in women after menopause:***

- 35 mg per week of RISEDRONATE

To prevent osteoporosis in women after menopause:

- 35 mg per week of RISEDRONATE

To increase bone density in men with osteoporosis:

- 35 mg per week of RISEDRONATE

Overdose:

If you take too much RISEDRONATE, drink a full glass of milk and tell your healthcare professional immediately. Do not make yourself vomit. Do not lie down.

If you think you, or a person you are caring for, have taken too much RISEDRONATE, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you missed your dose on your usual day, take one tablet in the morning after you remember. You can go back to your regular schedule for the next dose. If you have missed your dose by one week, do not take 2 tablets on the same day. Skip your missed dose and go back to your regular schedule.

What are possible side effects from using RISEDRONATE?

These are not all the possible side effects you may have when taking RISEDRONATE. If you experience any side effects not listed here, tell your healthcare professional.

Side effects may include:

- abdominal pain, heartburn, nausea
- diarrhea
- constipation
- flatulence (gas)
- headache
- lack of energy

When you take RISEDRONATE once a month, it may cause short-lasting, mild flu-like symptoms. These symptoms usually decrease as you keep taking doses.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Pain in bones, joints or muscles	√		
Esophagus and stomach problems: abdominal pain, pain or trouble swallowing, vomiting blood, heartburn, chest or breastbone pain, black or bloody stool			√
UNCOMMON			
Eye problems: eye pain, redness or swelling, sensitivity to light, decreased vision			√
RARE			
Pain in your tongue		√	
Jaw bone problems (osteonecrosis): numbness or a feeling of heaviness in the jaw; poor healing of gums; loose teeth; exposed bone in the mouth; sores in the mouth; discharge; dry mouth; swelling gums; infections; bad breath; pain in the mouth, teeth or jaw		√	
VERY RARE			
Allergic reactions: hives, rash (with or without blisters); swelling of the face, lips, tongue or throat; difficult or painful swallowing; trouble breathing			√
Hypocalcemia (low levels of calcium in the blood): numbness, tingling or muscle spasms		√	
Atypical femur fractures: new or unusual pain in the hip, groin or thigh		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

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.

Storage:

Keep RISEDRONATE in the original package and store in a dry place at room temperature (15°C to 30°C).

Keep out of reach and sight of children.

If you want more information about RISEDRONATE:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); the manufacturer's website (www.sivem.ca), or by calling 1-855-788-3153.

This leaflet was prepared by Sivem Pharmaceuticals ULC.

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