

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

Pr RISEDRONATE-35
Risedronate sodium (as monohydrate)
Manufacturer's Standard

Read this carefully before you start taking RISEDRONATE-35 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-35.

What is RISEDRONATE-35 used for?

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

How does RISEDRONATE-35 work?

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 and hip). Spine fractures may result in a curved back, height loss or back pain. RISEDRONATE-35 slows down bone loss which can help to reduce the risk of fractures. In many people RISEDRONATE-35 helps to increase bone density.

It is not known how long RISEDRONATE-35 should be used for treating osteoporosis. Keep talking to your doctor about whether RISEDRONATE-35 is still right for you.

RISEDRONATE-35 is not a pain reliever.

What are the ingredients in RISEDRONATE-35?

Medicinal ingredients: Risedronate sodium

Non-medicinal ingredients: Colloidal silicon dioxide, lactose monohydrate, magnesium stearate, pregelatinized starch, sodium stearyl fumarate, starch and film-coating containing the following: FD&C yellow #6/sunset yellow FCF aluminium lake, hydroxypropyl methylcellulose, iron oxide red, iron oxide yellow, polyethylene glycol, polysorbate and titanium dioxide.

RISEDRONATE-35 comes in the following dosage forms:

RISEDRONATE-35 is available as tablets. Each orange tablet contains: risedronate sodium 35 mg.

Do not use RISEDRONATE-35 if:

- You have low levels of calcium in your blood (hypocalcemia).
- You are allergic to risedronate sodium or any of the other ingredients in RISEDRONATE-35.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take RISEDRONATE-35. Talk about any health conditions or problems you may have, including if you:

- have/had problems swallowing or have problems with your esophagus (the tube that connects your mouth to your stomach)
- have/had stomach or digestive problems
- have/had kidney problems
- cannot stand or sit upright for at least 30 minutes (see How to take RISEDRONATE-35)
- are pregnant or breastfeeding
- have one of the following risk factors: cancer, diabetes, chemotherapy, radiotherapy of the head or neck, lowered immune system (immunosuppression), poor oral hygiene, treatment with corticosteroids or cancer drugs such as angiogenesis inhibitors (drugs that slow down the growth of new blood vessels)
- had/have pain, swelling or numbness of the jaw or loosening of a tooth or any other oral symptoms
- have sores in the mouth. This can lead to osteonecrosis of the jaw

Your doctor may check you if you:

- smoke
- have or have had teeth and/or gum disease
- have dentures that do not fit well
- have other relevant medical conditions at the same time, such as: low red blood cell count (called anemia) or if your blood cannot form clots in the normal way.

Your doctor may tell you to stop taking RISEDRONATE-35 until all sores in your mouth are healed.

Other warnings you should know about:

Your doctor should check your mouth and may ask you to see your dentist before you start taking RISEDRONATE-35. Dental work should be done before you start RISEDRONATE-35 treatment. Take good care of your teeth and gums and see the dentist for regular check-ups while taking RISEDRONATE-35.

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-35.

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-35:

Vitamins, mineral supplements and antacids may contain substances that can stop your body from absorbing RISEDRONATE-35. They include calcium, magnesium, aluminum and iron. Take these medicines at a different time of day than RISEDRONATE-35. Talk to your health care provider about how and when to take these medications.

Taking RISEDRONATE-35 with corticosteroids or cancer drugs may increase your chance of jaw bone problems (osteonecrosis of the jaw).

Talk to your doctor before taking pain medication like ASA or other non-steroidal anti-inflammatory drugs because they may upset your stomach.

How to take RISEDRONATE-35:

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

- Take RISEDRONATE-35 in the morning **on an empty stomach**, at least 30 minutes before you eat, drink or take other medicines.
- Swallow each RISEDRONATE-35 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-35

Usual Dose:

To treat osteoporosis in women after menopause:

- 1 tablet (35 mg) per week

To prevent osteoporosis in women after menopause:

- 1 tablet (35 mg) per week

To increase bone density in men with osteoporosis:

- 1 tablet (35 mg) per week

Overdose:

If you think you have taken too much RISEDRONATE-35, drink a full glass of milk. Do not make yourself vomit. Contact your healthcare professional, hospital emergency room or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

Weekly dose (35 mg):

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-35?

These are not all the possible side effects that you may feel when taking RISEDRONATE-35. If you experience any side effects not listed here, contact your healthcare professional.

Drugs like RISEDRONATE-35 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-35 and tell your doctor right away. Remember to take RISEDRONATE-35 as directed.

The most common side effects reported with RISEDRONATE-35 were:

- Abdominal pain, heartburn, nausea

RISEDRONATE-35 may cause pain in bones, joints or muscles, rarely severe.

Patients receiving RISEDRONATE-35 or other drugs in this class have reported:

- Rarely, non-healing jaw wounds.
- Very rarely, unusual fractures in their thigh bone.

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	✓		
Abdominal pain	✓		
UNCOMMON			
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 and skin reactions such as hives, rash (with or without blisters); swelling of the face, lips, tongue or throat; difficult or painful swallowing; trouble breathing.			✓
Symptoms of low levels of calcium in the blood such as numbness, tingling or muscle spasms.		✓	
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, talk to 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 (<https://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-35 in the original package and store at controlled room temperature (15°C – 30°C). Protect from light.

Keep out of reach and sight of children.

If you want more information about RISEDRONATE-35:

- 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 (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>); the manufacturer's website <http://www.sivem.ca>; or by calling 1-855-788-3153.

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