

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

^{Pr}APO-RISEDRONATE Risedronate Sodium Tablets USP

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

What is APO-RISEDRONATE used for?

- Treatment of osteoporosis in postmenopausal women

How does APO-RISEDRONATE 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. APO-RISEDRONATE slows down bone loss which can help to reduce the risk of fractures. In many people APO-RISEDRONATE helps to increase bone density.

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

APO-RISEDRONATE is not a pain reliever.

What are the ingredient in APO-RISEDRONATE?

Medicinal ingredients: Risedronate Sodium

Non-medicinal ingredients: anhydrous lactose, colloidal silicon dioxide, crospovidone, hydroxypropyl cellulose, hydroxypropyl methylcellulose, indigotine Al Lake, magnesium stearate, polyethylene glycol, sodium phosphate dibasic anhydrous, sodium phosphate monobasic monohydrate and titanium dioxide.

What dosage forms it comes in:

APO-RISEDRONATE 150 mg is available as tablets. Each blue tablet contains risedronate sodium 150 mg.

Do not use APO-RISEDRONATE if:

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

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take APO-RISEDRONATE. 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 APO-RISEDRONATE)
 - 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).
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- 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 APO-RISEDRONATE 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 APO-RISEDRONATE. Dental work should be done before you start APO-RISEDRONATE treatment. Take good care of your teeth and gums and see the dentist for regular checkups while taking APO-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 APO-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 APO-RISEDRONATE:

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

Taking APO-RISEDRONATE 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 of APO-RISEDRONATE:

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

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

Usual dose:

To treat osteoporosis in women after menopause:

150 mg per month of APO-RISEDRONATE

Overdose:

If you think you have taken too much APO-RISEDRONATE, 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:**Monthly dose (150 mg):**

If you forget to take your monthly dose of APO-RISEDRONATE, take it next in the morning if it is more than 7 days away. Take your next dose on the regularly scheduled day.

If your next dose is less than 7 days away, wait until your next scheduled dose. Do not take more than 150 mg APO-RISEDRONATE within 7 days.

What are possible side effects from using APO-RISEDRONATE?

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

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

The most common side effects with APO-RISEDRONATE were:

- Abdominal pain, heartburn, nausea

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

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

Patients receiving APO-RISEDRONATE 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 APO-RISEDRONATE and all other medications out of the reach and sight of children.
- Keep the tablets in their original package and store at controlled room temperature (15° to 30°C).
- Do not keep medicine that is out of date or that you no longer need.

If you want more information about APO-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 (<https://www.canada.ca/en/health-canada.html>); the manufacturer's website <http://www.apotex.ca/products>, or by calling 1-800-667-4708.

This leaflet was prepared by Apotex Inc., Toronto, Ontario, M9L 1T9.

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