

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PATIENT MEDICATION INFORMATION

^{Pr}**pms-RISEDRONATE**
Risedronate Sodium Tablets, USP
(as the hemi-pentahydrate)

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

What is pms-RISEDRONATE used for?

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

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

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

pms-RISEDRONATE is not a pain reliever.

What are the ingredients in pms-RISEDRONATE?

Medicinal Ingredients: Risedronate sodium

Non-medicinal ingredients:

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.

150 mg: Crospovidone, FD&C Blue #2 Indigo Carmine Aluminium Lake, Hydroxypropyl Cellulose, Hypromellose, Magnesium Stearate, Microcrystalline Cellulose, Polyethylene Glycol/Macrogol, Silica, Titanium Dioxide.

pms-RISEDRONATE comes in the following dosage forms:

Tablets: 35 mg and 150 mg

Do not use pms-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 pms-RISEDRONATE.

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

- have had problems or disease in your kidneys, esophagus (the tube connecting the mouth and the stomach),
- 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 pms-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).
- 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 pms-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 pms-RISEDRONATE. Dental work should be done before you start pms-RISEDRONATE treatment. Take good care of your teeth and gums and see the dentist for regular checkups while taking pms-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 pms-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 pms-RISEDRONATE:

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

Taking pms-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 on an empty stomach.

How to take pms-RISEDRONATE:

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

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

Usual dose:

To treat osteoporosis in women after menopause:

- 35 mg per week of pms-RISEDRONATE
- 150 mg per month of pms-RISEDRONATE

To prevent osteoporosis in women after menopause:

- 35 mg per week of pms-RISEDRONATE

To increase bone density in men with osteoporosis:

- 35 mg per week of pms-RISEDRONATE

Overdose:

If you think you have taken too much pms-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:

Weekly dose (35 mg tablet): 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.

Once monthly dose (150 mg tablet): If you forget to take your monthly dose of pms-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 of pms-RISEDRONATE within 7 days.

What are possible side effects from using pms-RISEDRONATE?

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

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

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

- Abdominal pain, heartburn, nausea

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

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

Patients receiving pms-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 inflammation; sensitivity to light, decreased vision			√
Rare			
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, swelling gum, infections, bad breath or pain in the mouth, teeth or jaw.		√	

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	
Very rare			
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		√	

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 SUSPECTED 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 pms-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.

If you want more information about pms-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/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.pharmascience.com, or by calling 1-888-550-6060.

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