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(For additional information [see "Risedronate: Drug information"](#))

You must carefully read the "Consumer Information Use and Disclaimer" below in order to understand and correctly use this information.

Brand Names: US

Actonel; Atelvia

Brand Names: Canada

Actonel; Actonel DR; APO-Risedronate; APO-Risedronate DR; Auro-Risedronate; DOM-Risedronate; JAMP-Risedronate; MYLAN-Risedronate [DSC]; PMS-Risedronate; Risedronate-35; RIVA-Risedronate; SANDOZ Risedronate; TEVA-Risedronate

What is this drug used for?

- It is used to treat Paget's disease.
- It is used to prevent or treat soft, brittle bones (osteoporosis).

What do I need to tell my doctor BEFORE I take this drug?

- If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell your doctor about the allergy and what signs you had.
- If you have any of these health problems: Esophagus problems, trouble swallowing, low calcium levels, or kidney disease.
- If you are not able to stand or sit up for 30 minutes.
- If you are taking any of these drugs: Cimetidine, dexlansoprazole, esomeprazole, famotidine, lansoprazole, nizatidine, omeprazole, pantoprazole, rabeprazole, or ranitidine.

- If you are taking another drug that has the same drug in it.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- Severe esophagus problems like irritation, swelling, ulcers, and bleeding have happened with this drug. Talk with the doctor.
- Worsening of asthma has happened in people taking drugs like this one. Talk with the doctor.
- This drug may raise the chance of a broken leg. Talk with the doctor.
- Have a bone density test as you have been told by your doctor. Talk with your doctor.
- Have blood work checked as you have been told by the doctor. Talk with the doctor.
- This drug may affect certain lab tests. Tell all of your health care providers and lab workers that you take this drug.
- This drug works best when used with calcium/vitamin D and weight-bearing workouts like walking or PT (physical therapy).
- Have a dental exam before starting this drug.
- Take good care of your teeth. See a dentist often.
- Talk with your doctor before you drink alcohol.
- If you smoke, talk with your doctor.

- A severe skin reaction (Stevens-Johnson syndrome/toxic epidermal necrolysis) may happen. It can cause severe health problems that may not go away, and sometimes death. Get medical help right away if you have signs like red, swollen, blistered, or peeling skin (with or without fever); red or irritated eyes; or sores in your mouth, throat, nose, or eyes.
- Tell your doctor if you are pregnant, plan on getting pregnant, or are breast-feeding. You will need to talk about the benefits and risks to you and the baby.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Signs of low calcium levels like muscle cramps or spasms, numbness and tingling, or seizures.
- Signs of high blood pressure like very bad headache or dizziness, passing out, or change in eyesight.
- Black, tarry, or bloody stools.
- Chest pain.
- Coughing up blood.
- Throwing up blood or throw up that looks like coffee grounds.
- Heartburn.
- Trouble swallowing.
- Very bad pain when swallowing.

- Sore throat.
- Very bad bone, joint, or muscle pain.
- Any new or strange groin, hip, or thigh pain.
- Change in eyesight, eye pain, or very bad eye irritation.
- Trouble passing urine.
- Pain when passing urine.
- This drug may cause jawbone problems. The risk may be higher with longer use, cancer, dental problems, ill-fitting dentures, anemia, blood clotting problems, or infection. It may also be higher if you have dental work, chemo, radiation, or take other drugs that may cause jawbone problems. Many drugs can do this. Talk with your doctor if any of these apply to you, or if you have questions. Call your doctor right away if you have jaw swelling or pain.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- Constipation, diarrhea, stomach pain, upset stomach, or throwing up.
- Back, muscle, or joint pain.
- Feeling dizzy, tired, or weak.
- Headache.
- Flu-like signs.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

All products:

- Take with plain water only. Avoid taking with mineral water, milk, or other drinks.
- Swallow whole. Do not chew, break, or crush.
- Do not suck on this product.
- Keep taking this drug as you have been told by your doctor or other health care provider, even if you feel well.

Regular-release tablets:

- Take with a full glass of water.
- Take at least 30 minutes before the first food, drink, or drugs of the day.
- Do not lie down for at least 30 minutes after taking this drug and until you eat your first food of the day.

Delayed-release tablets:

- Take after breakfast.
- Take with at least $\frac{1}{2}$ cup of water.
- Do not lie down or take other drugs for at least 30 minutes after taking this drug.

What do I do if I miss a dose?

- Do not take it later in the day.
- Take the missed dose on the next morning after you think about it and then go back to your normal time.
- Do not take 2 doses on the same day.
- If you are not sure what to do if you miss a dose, call your doctor.

How do I store and/or throw out this drug?

- Store at room temperature in a dry place. Do not store in a bathroom.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

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Consumer Information Use and Disclaimer

This information should not be used to decide whether or not to take this medicine or any other medicine. Only the healthcare provider has the knowledge and training to decide which medicines are right for a specific patient. This information does not endorse any medicine as safe, effective, or approved for treating any patient or health condition. This is only a brief summary of general information about this medicine. It does NOT include all

information about the possible uses, directions, warnings, precautions, interactions, adverse effects, or risks that may apply to this medicine. This information is not specific medical advice and does not replace information you receive from the healthcare provider. You must talk with the healthcare provider for complete information about the risks and benefits of using this medicine. The use of this information is governed by the Lexicomp End User License Agreement, available at <https://www.wolterskluwer.com/en/solutions/lexicomp/about/eula>.

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