

Medication Guide

Medication Guide
Actonel® (AK-toh-nel)
(*risedronate sodium*)
Tablets

Read the Medication Guide that comes with Actonel® before you start taking it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking with your doctor about your medical condition or your treatment. Talk to your doctor if you have any questions about Actonel.

What is the most important information I should know about Actonel?

Actonel can cause serious side effects including:

1. Esophagus problems
2. Low calcium levels in your blood (hypocalcemia)
3. Severe jaw bone problems (osteonecrosis)
4. Bone, joint, or muscle pain
5. Unusual thigh bone fractures

1. Esophagus problems.

Some people who take Actonel may develop problems in the esophagus (the tube that connects the mouth and the stomach). These problems include irritation, inflammation, or ulcers of the esophagus which may sometimes bleed.

- **It is important that you take Actonel exactly as prescribed to help lower your chance of getting esophagus problems. (See the section "How should I take Actonel?")**
- **Stop taking Actonel and call your doctor right away if you get chest pain, new or worsening heartburn, or have trouble or pain when you swallow.**

2. Low calcium levels in your blood (hypocalcemia).

Actonel may lower the calcium levels in your blood. If you have low blood calcium before you start taking Actonel, it may get worse during treatment. Your low blood calcium must be treated before you take Actonel. Most people with low blood calcium levels do not have symptoms, but some people may have symptoms. Call your doctor right away if you have symptoms of low blood calcium such as:

- Spasms, twitches, or cramps in your muscles
- Numbness or tingling in your fingers, toes, or around your mouth

Your doctor may prescribe calcium and vitamin D to help prevent low calcium levels in your blood, while you take Actonel. Take calcium and vitamin D as your doctor tells you to.

3. Severe jaw bone problems (osteonecrosis).

Severe jaw bone problems may happen when you take Actonel. Your doctor should examine your mouth before you start Actonel. Your doctor may tell you to see your dentist before you start Actonel. It is important for you to practice good mouth care during treatment with Actonel.

4. Bone, joint, or muscle pain.

Some people who take Actonel develop severe bone, joint, or muscle pain.

5. Unusual thigh bone fractures.

Some people have developed unusual fractures in their thigh bone. Symptoms of a fracture may include new or unusual pain in your hip, groin, or thigh.

Call your doctor right away if you have any of these side effects.

What is Actonel?

Actonel is a prescription medicine used to:

- Treat or prevent osteoporosis in women after menopause. Actonel helps increase bone mass and helps reduce the chance of having a spinal or non-spinal fracture (break).
- Increase bone mass in men with osteoporosis.
- Treat or prevent osteoporosis in either men or women who are taking corticosteroid medicines.
- Treat certain men and women who have Paget's disease of the bone.

It is not known how long Actonel works for the treatment and prevention of osteoporosis. You should see your doctor regularly to determine if Actonel is still right for you.

Actonel is not for use in children.

Who should not take Actonel?

Do not take Actonel if you:

- Have certain problems with your esophagus, the tube that connects your mouth with your stomach
- Cannot stand or sit upright for at least 30 minutes
- Have low levels of calcium in your blood

- Are allergic to Actonel any of its ingredients. A list of ingredients is at the end of this leaflet.

What should I tell my doctor before taking Actonel?

Before you start Actonel, be sure to talk to your doctor if you:

- Have problems with swallowing
- Have stomach or digestive problems
- Have low blood calcium
- Plan to have dental surgery or teeth removed
- Have kidney problems
- Have been told you have trouble absorbing minerals in your stomach or intestines (malabsorption syndrome)
- Are pregnant, or plan to become pregnant. It is not known if Actonel can harm your unborn baby.
- Are breastfeeding or plan to breastfeed. It is not known if Actonel passes into your milk and may harm your baby.

Especially tell your doctor if you take:

- antacids
- aspirin
- Nonsteroidal Anti-Inflammatory (NSAID) medicines

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements. Certain medicines may affect how Actonel works.

Know the medicines you take. Keep a list of them and show it to your doctor and pharmacist each time you get a new medicine.

How should I take Actonel?

- Take Actonel exactly as your doctor tells you. Your doctor may change your dose of Actonel if needed.
- **Actonel works only if taken on an empty stomach.**
- Take 1 Actonel tablet, **after** you get up for the day and **before** taking your first food, drink, or other medicine.
- Take Actonel while you are sitting or standing.
- **Do not chew or suck on a tablet of Actonel.**
- Swallow Actonel tablet with a full glass (6 to 8 oz) of plain water only.
- Do **not** take Actonel with mineral water, coffee, tea, soda, or juice.

After swallowing Actonel tablet, wait at least 30 minutes:

- Before you lie down. You may sit, stand or walk, and do normal activities like reading.
- Before you take your first food or drink except for plain water.

- Before you take other medicines, including antacids, calcium, and other supplements and vitamins.

Do not lie down for at least 30 minutes after you take Actonel and after you eat your first food of the day.

If you miss a dose of Actonel, **do not** take it later in the day. Take your missed dose the next morning and then return to your normal schedule. Do not take 2 doses at the same time.

If you miss more than 2 doses of Actonel in a month, call your doctor for instructions.

If you take too much Actonel, call your doctor. Do not try to vomit. Do not lie down.

What are the possible side effects of Actonel?

Actonel may cause serious side effects:

- See **“What is the most important information I should know about Actonel?”**

The most common side effects of Actonel are:

- pain, including back and joint pain
- stomach area (abdominal) pain
- heartburn

You may get allergic reactions, such as hives or, in rare cases, swelling of your face, lips, tongue, or throat.

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of Actonel. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store Actonel?

- Store Actonel at room temperature, 68° F to 77° F (20° C to 25° C).

Safely throw away medicine that is out of date or no longer needed.

Keep Actonel and all medicines out of the reach of children.

General information about the safe and effective use of Actonel.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Actonel for a condition for which it was not prescribed. Do not give Actonel to other people, even if they have the same symptoms you have. It may harm them.

This Medication Guide summarizes the most important information about Actonel. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about Actonel that is written for health professionals.

For more information, go to www.actonel.com or call 1-800-521-8813.

What are the ingredients in Actonel?

Active ingredient: risedronate sodium

Inactive ingredients in all dose strengths: crospovidone, hydroxypropyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, silicon dioxide, titanium dioxide.

Inactive ingredients specific to a dose strength: 5 mg—ferric oxide yellow, lactose monohydrate; 30 mg—lactose monohydrate; 35 mg—ferric oxide red, ferric oxide yellow, lactose monohydrate; 75 mg—ferric oxide red; 150 mg—FD&C blue #2 aluminum lake.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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Manufactured by:

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Manati, Puerto Rico 00674

or

Norwich Pharmaceuticals, Inc.,
North Norwich, NY 13814

or

Chinoin Pharmaceutical and Chemical Works Private Co. Ltd
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Marketed by:

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