

Medication Guide

Actonel[®] (AK-toh-nel) with Calcium *(risedronate sodium and calcium carbonate)* **Tablets**

Read the Medication Guide that comes with Actonel[®] with Calcium 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 treatment. Talk to your doctor if you have any questions about Actonel with Calcium, there may be new information about it.

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

Actonel with Calcium 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 with Calcium 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 with Calcium exactly as prescribed to help lower your chance of getting esophagus problems. (See the section “How should I take Actonel with Calcium?”)**
- **Stop taking Actonel with Calcium 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 with Calcium may lower the calcium levels in your blood. If you have low blood calcium before you start taking Actonel with Calcium, it may get worse during treatment. Your low blood calcium must be treated before you take Actonel with Calcium. 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 with Calcium. 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 with Calcium. Your doctor should examine your mouth before you start Actonel with Calcium. Your doctor may tell you to see your dentist before you start Actonel with Calcium. It is important for you to practice good mouth care during treatment with Actonel with Calcium.

4. Bone, joint, or muscle pain.

Some people who take Actonel with Calcium 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 with Calcium?

Actonel with Calcium is a prescription medicine used to:

- Treat or prevent osteoporosis in women after menopause. Actonel with Calcium helps increase bone mass and helps reduce the chance of having a spinal or non-spinal fracture (break).

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

Actonel with Calcium is not for use in children.

Who should not take Actonel with Calcium?

Do not take Actonel with Calcium if you:

- Have certain problems with your esophagus, the tube that connects your mouth with your stomach
- Have low levels of calcium in your blood
- Are allergic to Actonel or any of its ingredients. A list of ingredients is at the end of this leaflet.
- Cannot stand or sit upright for at least 30 minutes

Do not take Calcium if you:

- have high levels of calcium in your blood
- are allergic to Actonel with Calcium or any of its ingredients. A list of ingredients is at the end of this leaflet

What should I tell my doctor before taking Actonel with Calcium?

Before you start Actonel with Calcium, 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. You and your doctor should decide if you will take Actonel with Calcium or breastfeed. You should not do both.

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 with Calcium works.

Especially tell your doctor if you take:

- antacids
- aspirin
- Nonsteroidal Anti-Inflammatory (NSAID) medicines
- thyroid medicines
- antibiotics
- iron
- glucocorticoid medicines (steroid hormones)
- a diuretic (water pill)

Ask your doctor or pharmacist for a list of these medicines, if you are not sure.

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 with Calcium?

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

After swallowing Actonel with Calcium 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 with Calcium and after you eat your first food of the day.

Calcium:

- Take 1 Calcium tablet daily with food for the following 6 days of the week.

If you miss a dose of Actonel with Calcium, **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 with Calcium in a month, call your doctor for instructions.

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

What are the possible side effects of Actonel with Calcium?

Actonel with Calcium may cause serious side effects:

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

The most common side effects of Actonel with Calcium are:

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

You may get allergic reactions, such as hives, 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 with Calcium. 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 with Calcium?

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

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

General information about the safe and effective use of Actonel with Calcium

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Actonel with Calcium for a condition for which it was not prescribed. Do not give Actonel with Calcium 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 with Calcium. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about Actonel with Calcium that is written for health professionals.

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

What are the ingredients in Actonel with Calcium?

Actonel:

Active ingredient: risedronate sodium

Inactive ingredients: crospovidone, ferric oxide red, ferric oxide yellow, hydroxypropyl cellulose, hydroxypropyl methylcellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, silicon dioxide, titanium dioxide.

Calcium:

Active Ingredient: calcium carbonate

Inactive ingredients: pregelatinized starch, sodium starch glycolate, FD&C Blue #2, magnesium stearate, polyethylene glycol 3350, hypromellose, Opaspray Light Blue, polysorbate 80.

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

Actonel sold under U.S. patent No. 5,583,122; 5,935,602; 5,994,329; 6,015,801; 6,047,829; 6,096,342; 6,165,513; 6,225,294; 6,410,520; 6,432,932; 6,465,443; and 6,562,974.

Actonel manufactured by:
Warner Chilcott Company, LLC
Manati, Puerto Rico 00674
or
Norwich Pharmaceuticals, Inc.
North Norwich, NY 13814

Calcium manufactured by:
Norwich Pharmaceuticals, Inc.
North Norwich, NY 13814

Marketed by:
Warner Chilcott (US), LLC
Rockaway, NJ 07866
1-800-521-8813

0475G047

Revised 04/2013

To report SUSPECTED ADVERSE REACTIONS, contact Warner Chilcott at 1-800-521-8813 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

