

Patient Information ACTONEL® (AK-toh-nel) Tablets

ACTONEL (risedronate sodium tablets) 5 mg and ACTONEL (risedronate sodium tablets) 35 mg for Osteoporosis

Read this information carefully before you start to use your medicine. Read the information you get every time you get more medicine. There may be new information. This information does not take the place of talking with your health care provider about your medical condition or your treatment. If you have any questions or are not sure about something, ask your health care provider or pharmacist.

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

ACTONEL may cause problems in your stomach and esophagus (the tube that connects the mouth and the stomach), such as trouble swallowing (dysphagia), heartburn (esophagitis), and ulcers. You might feel pain in your bones, joints, or muscles (See “What are the Possible Side Effects of ACTONEL?”).

You must follow the instructions exactly for ACTONEL to work and to lower the chance of serious side effects. (See “How should I take ACTONEL?”).

What is ACTONEL?

ACTONEL is a prescription medicine used:

- to prevent and treat osteoporosis in postmenopausal women (See “What is Osteoporosis?”).
- to prevent and treat osteoporosis in men and women that is caused by treatment with steroid medicines such as prednisone.
- to treat Paget’s disease of bone (osteitis deformans). The treatment for Paget’s disease is very different than for osteoporosis and uses a different type of ACTONEL. This leaflet does not cover using ACTONEL for Paget’s disease. If you have Paget’s disease, ask your health care provider how to use ACTONEL.

ACTONEL may reverse bone loss by stopping more loss of bone and increasing bone mass in most people who take it, even though they won’t be able to see or feel a difference. ACTONEL helps lower the risk of breaking bones (fractures). Your health care provider may measure the thickness (density) of your bones or do other tests to check your progress.

See the end of this leaflet for information about osteoporosis.

Who should not take ACTONEL?

Do not take ACTONEL if you:

- have low blood calcium (hypocalcemia)
- cannot sit or stand up for 30 minutes
- have kidneys that work poorly
- have an allergy to ACTONEL. The active ingredient in ACTONEL is risedronate sodium. (See the end of this leaflet for a list of all the ingredients in ACTONEL.)

Tell your doctor before using ACTONEL if:

- you are pregnant or may become pregnant. We do not know if ACTONEL can harm your unborn child.
- you are breast-feeding or plan to breast-feed. We do not know if ACTONEL can pass through your milk and if it can harm your baby.
- you have kidney problems. ACTONEL may not be right for you.

Tell your health care providers that you are taking ACTONEL:

Many people have more than one health care provider who prescribes medicine or provides treatments. Be sure to tell all of your health care providers about the medicines that you take, including Actonel.

How should I take ACTONEL?

The following instructions are for both ACTONEL 5-mg (daily) and ACTONEL 35-mg (Once-a-Week):

- Take ACTONEL first thing in the morning before you eat or drink anything except plain water.
- Take ACTONEL while you are sitting or standing up.
- Take ACTONEL with 6 to 8 ounces (about 1 cup) of plain water. Do **not** take it with any other drink besides plain water. Do not take it with coffee, tea, juice, milk, or other dairy drinks.
- Swallow ACTONEL whole. Do not chew the tablet or keep it in your mouth to melt or dissolve.
- After taking ACTONEL you must wait at least 30 minutes **BEFORE**:
 - lying down. You may sit, stand, or do normal activities like read the newspaper or take a walk.
 - eating or drinking anything except plain water.
 - you take vitamins, calcium, or antacids. Take vitamins, calcium, and antacids at a different time of the day from when you take ACTONEL.
- Keep taking ACTONEL for as long as your health care provider tells you.
- For ACTONEL to treat your osteoporosis or keep you from getting osteoporosis, you have to take it as often and in the way it is prescribed.
- Your health care provider may tell you to take calcium and vitamin D supplements and to exercise.

What is my ACTONEL schedule?

If your doctor has prescribed ACTONEL 5-mg daily (a yellow tablet):

- Take 1 ACTONEL 5-mg tablet every day in the morning.
- If you forget to take your ACTONEL 5-mg in the morning, do **not** take it later in the day. Take only 1 ACTONEL 5-mg tablet the next morning and continue your usual schedule of 1 tablet a day. Do **not** take 2 tablets on the same day.

If your doctor has prescribed ACTONEL 35-mg Once-a-Week (an orange tablet):

- Choose 1 day of the week that you will remember and that best fits your schedule to take your ACTONEL 35-mg. Every week, take 1 ACTONEL 35-mg tablet in the morning on your chosen day.
- If you forget to take your ACTONEL 35-mg in the morning, do **not** take it later in the day. Take only 1 ACTONEL 35-mg tablet the next morning and continue your usual schedule of 1 tablet on your chosen day of the week. Do **not** take 2 tablets on the same day.

What should I avoid while taking ACTONEL?

- Do not eat or drink anything except water before you take ACTONEL and for at least 30 minutes after you take it.
- Do not lie down for at least 30 minutes after you take ACTONEL.
- Foods and some vitamin supplements and medicines can stop your body from absorbing (using) ACTONEL. Therefore, do not take the following products at or near the time you take ACTONEL: food, milk, calcium supplements, or calcium-, aluminum-, or magnesium-containing medicines, such as antacids. (See “How should I take ACTONEL?”).

What are the possible side effects of ACTONEL?

Stop taking ACTONEL and tell your health care provider right away if:

- **swallowing is difficult or painful**
- **you have chest pain**
- **you have very bad heartburn or it doesn't get better**

ACTONEL may cause:

- pain or trouble swallowing (dysphagia)
- heartburn (esophagitis)
- ulcers in your stomach and esophagus (the tube that connects the mouth and the stomach)
- pain in bones, joints or muscles, sometimes severe. Pain may start as soon as one day or up to several months after starting ACTONEL.

For patients with osteoporosis, the overall occurrence of side effects with ACTONEL was similar to placebo (sugar pill) and most were either mild or moderate. The most common side effects with ACTONEL include back pain, joint pain, upset stomach, abdominal (stomach area) pain, constipation, diarrhea, gas, and headache. Tell your health care provider if you have pain or discomfort in your stomach or esophagus. Rarely, severe skin reactions may occur. Patients may get allergic reactions such as rash, hives, or in rare cases, swelling that can be of the face, lips, tongue, or throat, which may cause trouble breathing or swallowing.

These are not all the possible side effects of ACTONEL. You can ask your health care provider or pharmacist about other side effects. Any time you have a medical problem you think may be from ACTONEL, talk to your doctor.

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What is osteoporosis?

Osteoporosis is a disease that causes bones to become thinner. Thin bones can break easily. Most people think of their bones as being solid like a rock. Actually, bone is living tissue, just like other parts of the body – your heart, brain, or skin, for example. Bone just happens to be a harder type of tissue. Bone is always changing. Your body keeps your bones strong and healthy by replacing old bone with new bone.

Osteoporosis causes the body to remove more bone than it replaces. This means that bones get weaker. Weak bones are more likely to break. Osteoporosis is a bone disease that is quite common, especially in older women. However, young people and men can develop osteoporosis, too. Osteoporosis can be prevented, and with proper therapy it can be treated.

How can osteoporosis affect me?

- You may not have any pain or other symptoms when osteoporosis begins.
- You are more likely to break (fracture) a bone especially if you fall because osteoporosis makes your bones weaker. You are most likely to break a bone in your back (spine), wrist, or hip.
- You may “shrink” (get shorter).
- You may get a “hump” (curve) in your back.
- You may have bad back pain that makes you stop some activities.

Who is at risk for osteoporosis?

Many things put people at risk for osteoporosis. The following people have a higher chance of getting osteoporosis:

Women who

- are going through or who are past menopause (“the change”)
- are white (Caucasian) or Asian

People who

- are thin
- have a family member with osteoporosis
- do not get enough calcium or vitamin D
- do not exercise
- smoke
- drink alcohol often
- take bone thinning medicines (like prednisone or other corticosteroids) for a long time

General information about ACTONEL:

Medicines are sometimes prescribed for conditions that are not mentioned in patient information leaflets. 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.

What if I have other questions about ACTONEL?

This leaflet summarizes the most important information about ACTONEL for osteoporosis. If you have more questions about ACTONEL, ask your health care provider or pharmacist. They can give you information written for health care professionals. For more information, call 1-877-**ACTONEL** (toll-free) or visit our web site at www.actonel.com.

What are the ingredients of ACTONEL?

ACTONEL (active ingredient): risedronate sodium.

ACTONEL (inactive ingredients): crosopvidone, ferric oxide red (35-mg tablets only), ferric oxide yellow, hydroxypropyl cellulose, hydroxypropyl methylcellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, silicon dioxide, and titanium dioxide.