

Patient Information
ACTONEL® (AK-toh-nel) Tablets
ACTONEL (risedronate sodium) tablets 5 mg,
ACTONEL (risedronate sodium) tablets 35 mg,
ACTONEL (risedronate sodium) tablets 75 mg, and
ACTONEL (risedronate sodium) tablets 150 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 healthcare provider about your medical condition or your treatment. If you have any questions or are not sure about something, ask your healthcare 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.
- to increase bone mass in men with 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 in men and women. The treatment for Paget’s disease is very different than for osteoporosis and uses a different dose of ACTONEL. This leaflet does not cover using ACTONEL for Paget’s disease. If you have Paget’s disease, ask your healthcare provider how to use ACTONEL.

ACTONEL may reverse bone loss by stopping more loss of bone and increasing bone strength 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 healthcare provider may measure the thickness (density) of your bones or do other tests to check your progress.

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 doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements. ACTONEL can interact with other medicines. Keep a list of all the medicines you take. Show it to all your healthcare providers, including your dentist and pharmacist, each time you get a new medicine.

How should I take ACTONEL?

The following instructions apply to all patients taking ACTONEL:

- Take ACTONEL exactly as prescribed by your healthcare provider.
- Take ACTONEL first thing in the morning before you eat or drink anything except plain water.
- Take ACTONEL while you are sitting up or standing.
- Take ACTONEL with 6 to 8 ounces (about 1 cup) of plain water. Do **not** take it with any other drink besides plain water.
- 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.
 - taking 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 healthcare provider tells you.
- For ACTONEL to treat your osteoporosis or keep you from getting osteoporosis, you have to take it exactly as prescribed.
- If you miss a dose of ACTONEL, call your healthcare provider for instructions.
- If you take more than your prescribed dose of ACTONEL, call your healthcare provider right away.
- Your healthcare provider may tell you to take calcium and vitamin D supplements and to exercise.

What is my ACTONEL schedule?

ACTONEL tablets are made in 4 different dosages (amounts). How often you should take your tablet depends upon the dosage that your doctor has prescribed (recommended) for you.

- 5 mg tablets are yellow. One tablet should be taken every day in the morning.
- 35 mg tablets are orange. One tablet should be taken once a week in the morning.
- 75 mg tablets are pink. One tablet should be taken in the morning two days in a row every month.
- 150 mg tablets are blue. One tablet should be taken once a month in the morning.

If you miss your dose in the morning, do not take it later in the day. You should call your healthcare provider for instructions.

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. See “How should I take ACTONEL?”.
- 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 anything other than plain water at or near the time you take ACTONEL.

What are the possible side effects of ACTONEL?

Stop taking ACTONEL and tell your healthcare provider right away if:

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

Possible serious side effects may include:

- esophagus or stomach problems, including ulcers, pain, or trouble swallowing. Tell your healthcare provider if you have pain or discomfort in your stomach or esophagus.
- low calcium and other mineral disturbances. If you already have one (or more) of these problems, it should be corrected before taking ACTONEL.
- pain in bones, joints or muscles, sometimes severe. Pain may start as soon as one day or up to several months after starting ACTONEL.
- jaw-bone problems in some people, which may include infection and slower healing after teeth are pulled. Tell your healthcare providers, including your dentist, right away if you have these symptoms.

Common side effects include the following:

- back and joint pain
- upset stomach and abdominal (stomach area) pain
- short-lasting, mild flu-like symptoms, which are reported with the monthly doses and usually get better after the first dose.

Other possible side effects may include:

- **Allergic and severe skin reactions.** Tell your healthcare provider if you develop any symptoms of an allergic reaction including: rash (with or without blisters), hives, or swelling of the face, lips, tongue, or throat. **Get medical help right away if you have trouble breathing or swallowing.**
- **Eye inflammation.** Tell your healthcare provider if you get any eye pain, redness, or if your eyes become more sensitive to light.

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 between 68°F to 77°F (20°C to 25°C).
- **Keep ACTONEL and all medicines out of the reach of children.**

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 healthcare provider or pharmacist. They can give you information written for healthcare 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):

All dose strengths contain: crospovidone, hydroxypropyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, silicon dioxide, titanium dioxide.

Dose-strength specific ingredients include: 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.

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Procter & Gamble Pharmaceuticals, Inc.

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and

sanofi-aventis U.S. LLC

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