

MEDICATION GUIDE
RISEDRONATE SODIUM
(RIS-e-DROE-nate SOE-dee-um)
DELAYED-RELEASE TABLETS

Rx only

Read this Medication Guide that comes with risedronate sodium delayed-release tablets 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 risedronate sodium delayed-release tablets, there may be new information about it.

What is the most important information I should know about risedronate sodium delayed-release tablets?

Risedronate sodium delayed-release tablets 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 risedronate sodium delayed-release tablets 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 risedronate sodium delayed-release tablets exactly as prescribed to help lower your chance of getting esophagus problems. (See the section “How should I take risedronate sodium delayed-release tablets?”)**
- **Stop taking risedronate sodium delayed-release tablets 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).

Risedronate sodium delayed-release tablets may lower the calcium levels in your blood. If you have low blood calcium before you start taking risedronate sodium delayed-release tablets, it may get worse during treatment. Your low blood calcium must be treated before you take risedronate sodium delayed-release tablets. 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 are taking risedronate sodium delayed-release tablets. 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 risedronate sodium delayed-release tablets. Your doctor should examine your mouth before you start risedronate

sodium delayed-release tablets. Your doctor may tell you to see your dentist before you start risedronate sodium delayed-release tablets. It is important for you to practice good mouth care during treatment with risedronate sodium delayed-release tablets.

4. Bone, joint, or muscle pain.

Some people who take risedronate sodium delayed-release tablets 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 are risedronate sodium delayed-release tablets?

Risedronate sodium delayed-release tablets are prescription medicine used to treat osteoporosis in women after menopause.

It is not known how long risedronate sodium delayed-release tablets works for the treatment and prevention of osteoporosis. You should see your doctor regularly to determine if risedronate sodium delayed-release tablets are still right for you.

Risedronate sodium delayed-release tablets are not for use in children.

Who should not take risedronate sodium delayed-release tablets?

Do not take risedronate sodium delayed-release tablets if you:

- Have certain problems with your esophagus, the tube that connects your mouth and stomach
- Cannot sit or stand up for at least 30 minutes
- Have low blood calcium (hypocalcemia)
- Are allergic to any of the other ingredients in risedronate sodium delayed-release tablets. See the end of this leaflet for a complete list of ingredients in risedronate sodium delayed-release tablets.

What should I tell my healthcare provider before taking risedronate sodium delayed-release tablets?

Before you take risedronate sodium delayed-release tablets, tell your healthcare provider if you:

- Have problems 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 mineral in your stomach or intestines (malabsorption syndrome)
- Are pregnant, plan to become pregnant, or suspect that you are pregnant. **If you become pregnant while taking risedronate sodium delayed-release tablets, stop taking it and contact your doctor.** It is not known if risedronate sodium delayed-release tablets can harm your unborn baby.
- Are breastfeeding or plan to breastfeed. It is not known if risedronate sodium passes into your breast milk and may harm your baby. You and your doctor should decide if you will take risedronate sodium delayed-release tablets 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 risedronate sodium delayed-release tablets works.

Especially tell your doctor if you take:

- Actonel® or other medicines to treat osteoporosis
- calcium supplements
- antacids
- laxatives
- iron supplements

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

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

How should I take risedronate sodium delayed-release tablets?

- Take risedronate sodium delayed-release tablets exactly as your doctor tells you.
- Take risedronate sodium delayed-release tablets 1 time a week **right after breakfast**. Choose a day of the week to take risedronate sodium delayed-release tablets that best fits your schedule.
- Take risedronate sodium delayed-release tablets with at least 4 ounces (about 1-half cup) of plain water.
- Swallow risedronate sodium delayed-release tablets whole. **Do not chew, cut, or crush** risedronate sodium delayed-release tablets before swallowing. If you cannot swallow risedronate sodium delayed-release tablets whole, tell your doctor. You may need a different medicine.

After swallowing risedronate sodium delayed-release tablets wait at least 30 minutes:

- Before you lie down. You may sit, stand or walk, and do normal activities like reading.
- 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 risedronate sodium delayed-release tablets.

If you miss your weekly risedronate sodium delayed-release tablets dose, take risedronate sodium delayed-release tablets the morning after you remember then return to your normal schedule. Do not take 2 doses at the same time.

You should take calcium and vitamin D as directed by your doctor.

If you take too much risedronate sodium delayed-release tablets, call your doctor. Do not try to vomit. Do not lie down.

What are the possible side effects of risedronate sodium delayed-release tablets?

Risedronate sodium delayed-release tablets may cause serious side effects:

- See **“What is the most important information I should know about risedronate sodium delayed-release tablets”**.

The most common side effects of risedronate sodium delayed-release tablets include:

- diarrhea
- flu-like symptoms
- muscle pain

- back and joint pain
- upset stomach
- stomach area (abdominal) pain

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 risedronate sodium delayed-release tablets. 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 risedronate sodium delayed-release tablets?

- Store risedronate sodium delayed-release tablets between 68° F to 77° F (20° C to 25° C).

Keep risedronate sodium delayed-release tablets and all medicines out of the reach of children.

General information about the safe and effective use of risedronate sodium delayed-release tablets

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information Leaflet. Do not use risedronate sodium delayed-release tablets for a condition for which it was not prescribed. Do not give risedronate sodium delayed-release tablets 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 risedronate sodium delayed-release tablets. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about risedronate sodium delayed-release tablets that is written for health professionals.

What are the ingredients in risedronate sodium delayed-release tablets?

Active ingredient: risedronate sodium (amorphous)

Inactive ingredients: Colloidal silicon dioxide, edetate disodium, ferric oxide yellow, hypromellose, lactose monohydrate, methacrylic acid copolymer, microcrystalline cellulose, polysorbate 80, sodium starch glycolate, sodium stearyl fumarate, talc, and triethyl citrate. The imprinting ink contains ferric oxide black, propylene glycol, and shellac glaze.

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