

Medication Guide
Risedronate Sodium tablets, USP
(RIS-e-DROE-nate SOE-dee-um)

Read the Medication Guide that comes with risedronate sodium 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 tablets, there may be new information about it.

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

Risedronate sodium 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 breaks in thigh and other bones.

1. Esophagus problems.

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

4. Bone, joint, or muscle pain.

Some people who take risedronate sodium tablets develop severe bone, joint, or muscle pain.

5. Unusual breaks in thigh and other bones.

Some people have had unusual bone breaks, including the thigh bone, when taking risedronate sodium tablets. A break in the thigh bone can feel like a new pain in your hip, groin, or thigh. People taking risedronate sodium tablets can also have breaks in other bones.

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

What are risedronate sodium tablets?

Risedronate sodium tablets is a prescription medicine used to:

- Treat or prevent osteoporosis in women after menopause. Risedronate sodium tablet 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 risedronate sodium tablets works for the treatment and prevention of osteoporosis. You should see your doctor regularly to determine if risedronate sodium tablets are still right for you.

Risedronate sodium tablets are not for use in children.

Who should not take risedronate sodium tablets?

Do not take risedronate sodium tablets 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 risedronate sodium tablets or any of its ingredients. A list of ingredients is at the end of this leaflet.

What should I tell my doctor before taking risedronate sodium tablets?

Before you start risedronate sodium tablets, 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, plan to become pregnant, or suspect that you are pregnant. **If you become pregnant while taking risedronate sodium tablets, stop taking it and contact your doctor.** It is not known if risedronate sodium tablets can harm your unborn baby.
- Are breastfeeding or plan to breastfeed. It is not known if risedronate sodium passes into your milk and may harm your baby.

Especially tell your doctor if you take:

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

