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Medication Guide

Risedronate Sodium (RIS-e-DROE-nate SOE-dee-um) Tablets, USP

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 thigh bone fractures

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 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 tablets?

Risedronate sodium tablets are prescription medicines used to:

- Treat or prevent osteoporosis in women after menopause. Risedronate sodium tablets help increase bone mass and help 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 work 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

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 tablets work.

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 risedronate sodium tablets?

- Take risedronate sodium tablets exactly as your doctor tells you. Your doctor may change your dose of risedronate sodium tablets if needed.
- **Risedronate sodium tablets work only if taken on an empty stomach.**
- Take 1 risedronate sodium tablet, after you get up for the day and before taking your first food, drink, or other medicine.
- Take risedronate sodium tablet while you are sitting or standing.
- **Do not chew or suck on a tablet of risedronate sodium.**
- Swallow risedronate sodium tablet with a full glass (6 to 8 ounces) of plain water only.
- Do **not** take risedronate sodium tablet with mineral water, coffee, tea, soda, or juice.



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After swallowing risedronate sodium 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 risedronate sodium tablets and after you eat your first food of the day.

If you miss a dose of risedronate sodium tablets, 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 risedronate sodium tablets in a month, call your doctor for instructions.

If you take too many risedronate sodium tablets, call your doctor. Do not try to vomit. Do not lie down.

What are the possible side effects of risedronate sodium tablets?

Risedronate sodium tablets may cause serious side effects:

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

The most common side effects of risedronate sodium tablets 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 risedronate sodium 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 tablets?

- Store risedronate sodium tablets at 20° to 25°C (68° to 77°F); excursions permitted between 15° and 30°C (59° and 86°F).
- Risedronate sodium tablets come in a child-resistant package.

Safely throw away medicine that is out of date or no longer needed.

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

General information about the safe and effective use of risedronate sodium tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use risedronate sodium tablets for a condition for which it was not prescribed.

Do not give risedronate sodium 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 tablets. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about risedronate sodium tablets that is written for health professionals.

For more information, call 1-800-818-4555.

What are the ingredients in risedronate sodium tablets?

Active ingredient: risedronate sodium
Inactive ingredients in all dose strengths: mannitol, microcrystalline cellulose, croscarmellose sodium, pregelatinized maize starch, colloidal silicon dioxide, magnesium stearate, polyvinyl alcohol, titanium dioxide, polyethylene glycol, talc.

Inactive ingredients specific to a dose strength:
5 mg-iron oxide yellow; 35 mg- iron oxide red, iron oxide yellow; 75 mg- iron oxide red; 150 mg-FD&C blue #2 aluminum lake.

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

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