**CLINICAL PHARMACOLOGY**

- Abnormalities of the esophagus which delay esophageal emptying such as stricture or achalasia (4, 5.2)

**HIGHLIGHTS OF PRESCRIBING INFORMATION**

- Abdominal pain (6.1)

**ADVERSE REACTIONS**

To report SUSPECTED ADVERSE REACTIONS, contact Greenstone LLC at 1-800-438-1985 or FDA at [website] for additional information. Report of adverse reactions to: [address].

**DOSAGE AND ADMINISTRATION**

- Risedronate sodium should be taken 90 minutes before breakfast. Patients with pre-existing gastrointestinal disease and concomitant use of non-steroidal anti-inflammatory drugs are at greater risk for adverse reactions.

**DOSE FORMS AND STRENGTHS**

- Delayed-release tablets

**WARNINGS AND PRECAUTIONS (5.1)**

- Postmenopausal osteoporosis

**ADVERSE REACTIONS (6)**

- Abdominal pain (5.2% versus 2.9%), dyspepsia (3.9% versus 3.9%), upper abdominal pain (2.9% versus 2.3%), gastritis (1.0% versus 1.0%), and gastroesophageal reflux disease (1.0% versus 1.6%). Study discontinuation rate due to adverse reactions was 6.6% versus 5.3%

**DRUG INTERACTIONS (7.3)**

- Concomitant use of non-steroidal anti-inflammatory drugs (NSAIDs) and risedronate sodium was associated with increased risk of upper gastrointestinal adverse reactions.

**PRECAUTIONS (5)**

- Corticosteroids, chemotherapy, and angiogenesis inhibitors may increase the risk of upper gastrointestinal adverse reactions.

**CONTRAINDICATIONS (5.2)**

- Risedronate sodium is contraindicated in patients with known esophageal motility disorders that delay gastric emptying, such as esophageal stricture, achalasia, or motility disorders.

**ADDITIONAL INFORMATION (1)**

- The safety of Risedronate sodium 35 mg once-a-week in the treatment of postmenopausal osteoporosis was evaluated in two 3-year trials involving 1,000 postmenopausal women aged 38 to 85 years with postmenopausal osteoporosis. The duration of the trials was up to three years, with 500 mg of elemental calcium and 400 international units vitamin D included in the regimen. The incidence of new vertebral fractures (primary end point) was lower in the placebo group compared to the risedronate sodium immediate-release 5 mg daily group. The incidence of serious adverse reactions was 24.6% in the placebo group versus 18.4% in the risedronate sodium 5 mg daily group.

**CLINICAL STUDIES (14)**

- Treatment of Postmenopausal Osteoporosis

**REFERENCES (16)**

- For a complete list of references, please see the end of this leaflet for a complete list of references.
For all medical inquiries contact:

Patented. See www.allergan.com/patents.

How should I take Risedronate sodium?

• Take Risedronate sodium exactly as your doctor tells you. 

• Take Risedronate sodium 1 hour before a meal or 2 hours after a meal. 

• Take Risedronate sodium with a full glass of water. 

• Do not take Risedronate sodium right after a meal or 2 hours before a meal. 

• Do not lie down for at least 30 minutes after you take Risedronate sodium. 

If you forget to take Risedronate sodium, take it as soon as you remember it. Do not take more than 1 dose at the same time.

What is the possible side effects of Risedronate sodium?

The most common side effects of Risedronate sodium include:

• Abnormal dreams
• Anemia
• Headache
• Joint pain
• Sleep disturbance

These side effects may go away as your body gets used to this medicine. These side effects may not occur in everyone. If any of these side effects trouble you, talk with your doctor or pharmacist.

What should I avoid while taking Risedronate sodium?

• Do not lie down for at least 30 minutes after you take Risedronate sodium. 

• Do not take more than 1 dose at the same time. 

• Do not drive when you are taking Risedronate sodium. 

• Stop driving or operating heavy machines until you know how Risedronate sodium affects you. 

What is Risedronate sodium?

Risedronate sodium is indicated for the prevention and treatment of osteoporosis in postmenopausal women who are at high risk of fracture. 

General information about the safe and effective use of Risedronate sodium

Read this Medication Guide that comes with Risedronate sodium. Do not throw away any that you do not use. Keep your information about Risedronate sodium that is written for your medical profession.

For more information, go to www.greenstone.com or call 1-800-333-4515.

What are the ingredients in Risedronate sodium?

Active ingredients: risedronate sodium

Inactive ingredients: Stabilized sucrose, hydroxypropyl cellulose, sucrose, lactose, sodium lactate, stearic acid, magnesium stearate, yellow iron oxide, red iron oxide.

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

For medical inquiries contact: Greenstone LLC Medical Communications 1-800-333-4515 FAX: March 2017

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Table 4

<table>
<thead>
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<th>Condition</th>
<th>5 mg</th>
<th>6 mg</th>
<th>9 mg</th>
<th>12 mg</th>
<th>18 mg</th>
<th>25 mg</th>
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<td>0.8</td>
<td>5.0</td>
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<td>3.0</td>
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<td>Femoral Neck</td>
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<td>-0.3</td>
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</table>

Dosage and Administration

Instruct patients to take Risedronate sodium in the morning, while in an upright position (sitting or standing) with 8 oz (250 mL) of water. Instruct patients to take Risedronate sodium at least 1 hour before a meal.

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