Each tablet contains:
the equivalent of 35 mg of anhydrous risedronate sodium in the form of the monohydrate
Take as directed by prescriber.
Usual Dosage: See package insert for full prescribing information.
Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].
Take as directed by prescriber.

Usual dosage: See package insert for full prescribing information.

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

Dispense in a tight, light-resistant container as defined in the USP, with a child-resistant closure.

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

Manufactured For: TEVA PHARMACEUTICAL USA
Sellersville, PA 18960

Manufactured In Israel By: TEVA PHARMACEUTICAL IND. LTD.
Jerusalem, 91010, Israel

Each tablet contains: the equivalent of 30 mg of anhydrous risedronate sodium in the form of the monohydrate.

NDC 0093-7391-56
30 TABLETS
30 mg

RISEDRONATE SODIUM Tablets

Manufactured In Israel by TEVA PHARMACEUTICAL IND. LTD.
Jerusalem, 91010, Israel

Manufactured For: TEVA PHARMACEUTICAL USA
Sellersville, PA 18960

3 1/2 
3 1/2 "
1 3/4"
Take as directed by prescriber. See package insert for full prescribing information.

Usual Dosage: See package insert for full prescribing information.

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Dispense in a tight, light-resistant container as defined in the USP, with a child-resistant closure (as required).

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.
Take as directed by prescriber.

Usual Dosage: See package insert for full prescribing information.

Dispense in a tight, light-resistant container as defined in the USP, with a child-resistant closure (as required).

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

Keep this and all medications out of the reach of children.

Each tablet contains: the equivalent of 30 mg of anhydrous risedronate sodium in the form of the monohydrate.
Take as directed by prescriber. Usual Dosage: See package insert for full prescribing information.

NDC 0093-7390-56
Risedronate Sodium Tablets
5 mg

Each tablet contains: the equivalent of 5 mg of anhydrous risedronate sodium in the form of the monohydrate

Rx only

30 TABLETS

Manufactured For:
TEVA PHARMACEUTICALS USA
Sellersville, PA 18960

Manufactured In Israel By:
TEVA PHARMACEUTICAL IND. LTD.
Jerusalem, 91010, Israel

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].
Dispense in a tight, light-resistant container as defined in the USP, with a child-resistant closure (as required).

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

Iss. 1/2005

0093-7390-56

Each tablet contains: the equivalent of 5 mg of anhydrous risedronate sodium in the form of the monohydrate.
Risedronate Sodium Tablets
5 mg

Each tablet contains: the equivalent of 5 mg of anhydrous risedronate sodium in the form of the monohydrate

Take as directed by prescriber. See package insert for full prescribing information. Dispense in a light-resistant container as defined in the USP, with a child-resistant closure (as required).

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

Keep this and all medications out of the reach of children.

Manufactured in Israel by:
TEVA PHARMACEUTICAL IND. LTD.
Jerusalem, 91010, Israel

Iss. 12/2005
NDC 0093-7390-10

RISEDRONATE SODIUM
Tablets
5 mg

Each tablet contains: the equivalent of 5 mg of anhydrous risedronate sodium in the form of the monohydrate.

Take as directed by prescriber.

Usual Dosage: See package insert for full prescribing information.

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

Dispense in a light, light-resistant container as defined in the USP, with a child-resistant closure (as required).

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.
Take as directed by prescriber.

Usual Dosage: See package insert for full prescribing information.

Dispense in a tight, light-resistant container as defined in the USP, with a child-resistant closure (as required).

Store at 20°C to 25°C (68°F to 77°F) [See USP Controlled Room Temperature].

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

Manufactured For:
TEVA PHARMACEUTICALS USA
Sellersville, PA 18960

Manufactured In Israel By:
TEVA PHARMACEUTICAL IND. LTD.
Jerusalem, 91010, Israel

NDC 0093-7389-10
RISEDRONATE SODIUM Tablets
Once-a-Week
35 mg

Each tablet contains: the equivalent of 35 mg of anhydrous risedronate sodium in the form of the monohydrate

0093-7389-10

1000 TABLETS

0093-7389-10
Risedronate has an affinity for hydroxyapatite crystals in bone and acts as an inhibitor of osteoclast activity.

**Mechanism of Action**

Bioavailability and disposition are similar in elderly (> 60 years of age) and younger adults.

**Pharmacokinetics**

The time-concentration profile is multi-phasic, with a plasma half-life of about 1.5 hours and a terminal elimination half-life of 1-3 days. Approximately 90% of an oral dose is absorbed within 2 hours of administration, and absorption is complete within 4 hours. Risedronate is highly bound to plasma proteins (> 99%).

**Disposition**

Elimination is predominantly renal, with < 1% excreted unchanged in the urine. After oral administration, the highest concentrations are seen in the jejunum, ileum, and colon. Risedronate is not extensively metabolized: < 2% of a dose is excreted as metabolites in the urine.

**Contraindications**

Risedronate sodium tablets are contraindicated in patients with an inability to ingest, swallow, or retain oral tablets (e.g., due to esophageal disease), or who are at risk of developing osteoporosis and for whom the desired clinical outcome is to prevent bone fractures. Risedronate sodium tablets may be considered in postmenopausal women who are at risk of developing osteoporosis and who cannot use alendronate or etidronate disodium due to risk for esophageal irritation.

**Warnings**

- **Upper Gastrointestinal Disorders:** Risedronate sodium tablets may cause upper gastrointestinal disorders such as dysphagia, heartburn (esophagitis), and ulcers. You should not take risedronate sodium tablets if you have low blood calcium (hypocalcemia) or if you have stopped producing stomach acid due to a disease or taking certain medications. If you are taking risedronate sodium tablets, you should not start taking another medicine that causes your stomach to produce less acid without talking to your doctor.

**Precautions**

- **Drug Interactions:** Risedronate sodium tablets should be used with caution in patients with renal impairment. The safety and effectiveness of risedronate sodium tablets have not been fully established in patients with severe renal impairment (creatinine clearance < 30 mL/min).

**Special Populations**

- **Elderly:** Risedronate sodium tablets are generally well tolerated in elderly patients. The incidence of adverse events in elderly patients was similar to that in younger patients.

**Clinical Studies**

- **Bone Density:** Risedronate sodium tablets 5 mg daily significantly reduced bone mineral density (BMD) changes at the lumbar spine, femoral neck, femoral trochanter, and midshaft radius in these patients compared to placebo.

**Other Important Information**

- **Pharmacodynamics:** Risedronate sodium tablets 5 mg daily significantly reduced bone turnover in patients treated with risedronate. The reduction in risk seen in the placebo group to 5% in the risedronate treatment group was statistically significant relative to baseline and to placebo at 6 months and at all later time points.

**Table 3**

<table>
<thead>
<tr>
<th>Time (Years)</th>
<th>Placebo</th>
<th>Risedronate</th>
<th>Etidronate</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.3 ± 0.2</td>
<td>0.1 ± 0.1</td>
<td>0.2 ± 0.1</td>
</tr>
<tr>
<td>2</td>
<td>0.5 ± 0.3</td>
<td>0.2 ± 0.2</td>
<td>0.3 ± 0.2</td>
</tr>
<tr>
<td>3</td>
<td>0.6 ± 0.4</td>
<td>0.3 ± 0.3</td>
<td>0.4 ± 0.3</td>
</tr>
</tbody>
</table>

- **Notes:** All patients in this study were on average 14 years postmenopausal. The BMD results for patients 37 to 82 years, who were on average 14 years postmenopausal. The BMD results for these patients were normal at baseline (average T-score -0.7). All patients in this study were on average 14 years postmenopausal.
women. However, young people and men can develop heart, brain, or skin, for example. Bone just happens is living tissue, just like other parts of the body – your

What is osteoporosis?

In a double-blind, active-controlled study, the adverse event profile was similar for patients taking risedronate sodium tablets once a week compared to placebo. The most common adverse events reported in the risedronate and placebo groups were:

- flatulence
- diarrhea
- constipation
- abdominal (stomach area) pain

Serum phosphorus levels below 2 mg/dL were observed in 14 patients, 11 (0.6%) treated with risedronate sodium tablets and 3 (0.6%) placebo patients. Other laboratory abnormal results included:

- alkaline phosphatase levels above 3 times the upper limit of normal in 4 patients, 3 (0.6%) treated and 1 (0.2%) placebo
- creatinine clearance below 60 mL/min in 3 patients, 2 (0.4%) treated and 1 (0.2%) placebo
- sodium levels below 135 mEq/L in 3 patients, all from the placebo group
- calcium levels below 9 mg/dL in 2 patients, both from the placebo group

Following people have a higher chance of getting osteoporosis:

- women who have gone through menopause
- women who are past menopause
- women who are on hormone therapy
- women who have a family member with osteoporosis
- women who do not get enough calcium or vitamin D
- women who do not exercise
- women who are breast-feeding or plan to breast-feed
- women who are on hormone therapy
- women who are on corticosteroids or other bone thinning medicines
- women who have an allergy to risedronate. The active ingredient in risedronate sodium tablets is not recommended for use in patients with severe renal impairment (serum creatinine >3.5 mg/dL). However, patients with mild to moderate renal impairment (serum creatinine 1.5 to 3.5 mg/dL) and bone disease can be treated with risedronate sodium tablets. Researchers were encouraged to investigate the potential effect of risedronate sodium tablets on bone disease and concomitant use of NSAIDs or aspirin.

How can osteoporosis affect me?

You may “shrink” (get shorter). You are more likely to break (fracture) a bone. A fracture is a break in a bone that may cause extreme pain or difficulty. You may have bad back pain that makes you stop some activities.

When is a cause for concern?

Very rare reactions of eye inflammation including iritis and uveitis have been reported. In rare cases, patients taking risedronate sodium tablets may get eye inflammation, usually with pain, redness, and tearing.

In rare cases, patients taking risedronate sodium tablets may get eye inflammation, usually with pain, redness, and tearing. There are very rare adverse effects of fluoride for people. You can ask your health care provider or pharmacist about these side effects. Any time you have a medical problem you think may be from risedronate, talk to your doctor.

What is osteoporosis?

Osteoporosis is a disease that causes bones to become thinner. Bone can break easily when people don’t get enough calcium and vitamin D in their diet, or when they don’t get enough exercise. This makes bones more likely to break. Osteoporosis is a disease that causes bones to become weaker. Bones are more likely to break. Osteoporosis is a bone disorder that doesn’t cause any symptoms. However, people and men can develop osteoporosis, too. Osteoporosis can be prevented, and

How can osteoporosis affect me?

You may have any pain or other symptoms when osteoporosis begins.

How can osteoporosis affect me?

You are more likely to break (fracture) a bone because of osteoporosis if you fall because you can’t maintain your balance or you are not wearing your glasses or other eye injuries. You may have “shrink” (get shorter). You may have bad back pain that makes you stop some activities.

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