

Risedon[®] 150

Risedronate Sodium

Please read this entire leaflet carefully before you start taking this medicine.

- * Keep this leaflet. You may need to read it again.
- * If you have further questions, please ask your doctor
- * This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- * If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

WHAT Risedon[®] IS AND WHAT IT IS USED FOR?

Risedon[®] 150 tablet contains Risedronate Sodium INN 150 mg. **Risedon[®]** is in a group of medicines called bisphosphonates. It alters the cycle of bone formation and breakdown in the body. It slows bone loss while increasing bone mass, which may prevent bone fractures.

Risedon[®] is a prescription medicine used:

- * to prevent and treat osteoporosis in postmenopausal women.
- * to increase bone mass in men with osteoporosis.
- * to prevent and treat osteoporosis in men and women that is caused by treatment with steroid medicines such as prednisone.
- * to treat Paget's disease of bone in men and women.

About osteoporosis

Your body is constantly breaking down old bone and making new bone tissue. If you have osteoporosis, your body breaks down more bone than it forms so that gradually bone loss occurs and your bones become thinner and fragile. This is especially common in women after the menopause (change of life). Many people with osteoporosis have no symptoms and you may not even know that you have it. However, osteoporosis makes you more likely to have fractures (break bones), especially in your spine, hips and wrists.

How Risedon[®] works

Risedon[®] has an affinity for hydroxyapatite crystals in bone and acts as an antiresorptive agent. At the cellular level, **Risedon[®]** inhibits osteoclasts. The osteoclasts adhere normally to the bone surface, but show evidence of reduced active resorption.

BEFORE YOU TAKE Risedon[®]

Take special care with **Risedon[®]** if you:

- * have low blood calcium (hypocalcemia)
- * cannot sit or stand up for 30 minutes
- * have kidneys that work poorly
- * have an allergy to Risedronate Sodium

Before taking Risedon[®] talk to your doctor if you:

- * are pregnant or may become pregnant. We do not know if Risedronate Sodium can harm your unborn child.
- * are breast-feeding or plan to breast-feed. We do not know if Risedronate Sodium can pass through your milk and if it can harm your baby.
- * have kidney problems Risedronate Sodium may not be right for you.

Risedronate sodium is not intended for use in children.

During treatment, if you experience an allergic reaction (such as swelling of the face, tongue or throat, difficulty in breathing or swallowing, skin rash), you must stop taking Risedronate sodium and seek medical advice immediately. If you have stopped treatment due to hypersensitivity reactions you should not re-start therapy with Risedronate sodium.

Taking other medicines:

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription specially aspirin or other NSAIDs. Antacids, supplements, or medicines that contain aluminum, calcium, magnesium, or other minerals can interfere with how your body absorbs Risedronate Sodium. If you use these other medicines, do not take them for at least 30 minutes after taking a Risedronate Sodium tablet.

Pregnancy:

Risedronate Sodium is meant for use only in postmenopausal women. Therefore, Risedronate Sodium should not be taken during pregnancy. If you take it by accident during pregnancy, stop taking it straight away and talk to your doctor.

Breast-feeding:

Risedronate Sodium is meant for use only in postmenopausal women. Therefore, breast-feeding women should not take this medicine. If you take it by accident during breast-feeding, stop taking it straight away and talk to your doctor.

HOW TO TAKE Risedon[®]

One **Risedon[®] 150** tablet should be taken once a month in the morning. You have to take the tablet on a fixed day of every month.

The following instructions apply to all patients taking Risedon[®]:

- * Take **Risedon[®] 150** exactly as prescribed by your healthcare provider.
- * Take **Risedon[®] 150** in the morning before you eat or drink anything except plain water.
- * Take **Risedon[®] 150** while you are sitting up or standing.
- * Take a **Risedon[®] 150** with 1 glass of plain water. Do not take it with any other drink besides plain water.
- * Swallow **Risedon[®] 150** whole. Do not chew the tablet or keep it in your mouth to melt or dissolve.
- * After taking **Risedon[®] 150** you must wait at least 30 minutes before:
 1. lying down. You may sit, stand, or do normal activities like read the newspaper or take a walk.
 2. eating or drinking anything except plain water.
 3. taking vitamins, calcium, or antacids.
- * Take vitamins, calcium, and antacids at a different time of the day from when you take **Risedon[®] 150**.
- * Keep taking **Risedon[®] 150** for as long as your healthcare provider tells you.

If you take more Risedon[®] 150 than you should:

Seek emergency medical attention if you think you have used too much of this medicine. Drink a full glass of milk right away. Do not make yourself vomit and do not lie down.

Overdose symptoms may include nausea, heartburn, stomach pain, diarrhea, muscle cramps, numbness or tingling, tight muscles in your face, seizure (convulsions), irritability, and unusual thoughts or behavior.

If you forget to take Risedon[®] 150

If you forget to take **Risedon[®] 150** on your scheduled day, take it in the morning on the day after you remember the missed dose. Then return to your regular monthly schedule on your chosen dose day. Do not take two (2) tablets in one day.

POSSIBLE SIDE EFFECTS

Serious side effects:

- * chest pain;
- * difficulty or pain when swallowing;
- * pain or burning under the ribs or in the back;
- * new or worsening heartburn;
- * severe joint, bone, or muscle pain; or
- * jaw pain, numbness, or swelling.

Less serious side effects:

- * mild heartburn or stomach upset;
- * diarrhea, gas, or constipation;
- * mild joint or back pain;
- * headache.

HOW TO STORE

Store in a cool and dry place. Protect from light & moisture. Keep out of the reach of children.

HOW SUPPLIED

Contents of the pack

Risedon[®] 150 Tablet: Each box containing 1 tablet in Alu-Alu pack.

Manufactured by :



SQUARE
PHARMACEUTICALS LTD.
BANGLADESH

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