



Risedon™ Plus

Risedronate Sodium 35 mg & Calcium 500 mg

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 or your pharmacist.
- 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™ Plus IS AND WHAT IT IS USED FOR?

Risedon™ Plus is a co-package product containing 1 tablet of Risedronate Sodium INN 35 mg for once weekly dosing and 6 tablets of Calcium Carbonate BP equivalent to 500 mg Calcium for daily dosing of the remaining 6 days of the week.

Risedronate 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.

INDICATION

- 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 prednisolone.
- 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™ Plus WORKS?

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

Calcium suppresses parathyroid hormone (PTH) secretion and decreases bone turnover. Increased levels of PTH are known to contribute to age-related bone loss, especially at cortical sites, while increased bone turnover is an independent risk factor of fractures.

PRECAUTION

Take special care with 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.
- are pregnant or may become pregnant.
- are breast-feeding or plan to breast-feed.
- have kidney problems, Risedronate Sodium may not be right for you.

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 the absorption of Risedronate Sodium. If you use these other medicines, do not take these for at least 30 minutes after taking a Risedronate Sodium tablet.

PREGNANCY

It should not be taken during pregnancy. If you take it by accident during pregnancy, stop taking it straight away and talk to your doctor.

LACTATION

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.

FOR RENAL IMPAIRED PATIENTS

Risedronate Sodium is not recommended for use in patients with severe renal impairment (creatinine clearance <30 ml/min). No dosage adjustment is necessary in patients with a creatinine clearance ≥30 ml/min or in the elderly.

HOW TO TAKE Risedon™ Plus TABLET?

The following instructions are applicable to all patients taking Risedon tablet:

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

WHAT IS MY Risedon™ Plus SCHEDULE?

One Risedon tablet should be taken orally once a week (Day 1 of the 7-day treatment cycle). One calcium 500 mg tablet should be taken orally with food daily on each of the remaining six days (Days 2 through 7 of the 7-day treatment cycle).

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, jaw pain, numbness, or swelling, 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

Risedon™ Plus: Each box contains 4 blisters of **Risedon™ Plus** having 1 tablet of Risedronate Sodium with 6 tablets of Calcium Carbonate in each blister.

Manufactured by



SQUARE
PHARMACEUTICALS LTD.

Pabna, Bangladesh

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