Risedronate sodium 35 mg film-coated tablets

Risedronate sodium

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is this leaflet:
1. What Risedronate sodium is and what it is used for
2. What you need to know before you take Risedronate sodium
3. How to take Risedronate sodium
4. Possible side effects
5. How to store Risedronate sodium
6. Contents of the pack and other information

1. What Risedronate sodium is and what it is used for

What Risedronate sodium is
Risedronate sodium belongs to a group of non-hormonal medicines called bisphosphonates which are used to treat bone diseases. It works directly on your bones to make them stronger and therefore less likely to break.

Bone is a living tissue. Old bone is constantly removed from your skeleton and replaced with new bone.

Postmenopausal osteoporosis is a condition occurring in women after the menopause where the bones become weaker, more fragile and more likely to break after a fall or strain. Osteoporosis can also occur in men due to a number of causes including ageing and/or a low level of the male hormone, testosterone.

The spine, hip and wrist are the most likely bones to break, although this can happen to any bone in your body. Osteoporosis-related fractures can also cause back pain, height loss and a curved back. Many patients with osteoporosis have no symptoms and you may not even have known that you had it.

What Risedronate sodium is used for
The treatment of osteoporosis
- in postmenopausal women, even if osteoporosis is severe. It reduces the risk of spinal and hip fractures.
- in men.

2. What you need to know before you take Risedronate sodium

Do not take Risedronate sodium:
- if you are allergic to risedronate sodium or any of the other ingredients of this medicine (listed in section 6)
- if your doctor has told you that you have a condition called hypocalcaemia (a low blood calcium level)
- if you may be pregnant, are pregnant or planning to become pregnant
- if you are breast-feeding
- if you have severe kidney problems.

**Warnings and precautions**

Talk to your doctor or pharmacist before taking Risedronate sodium
- if you are unable to stay in an upright position (sitting or standing) for at least 30 minutes.
- if you have abnormal bone and mineral metabolism (for example lack of vitamin D, parathyroid hormone abnormalities, both leading to a low blood calcium level).
- if you have had problems in the past with your oesophagus (the tube that connects your mouth with your stomach). For instance you may have had pain or difficulty in swallowing food or you have **previously** been told that you have Barratt’s oesophagus (a condition associated with changes in the cells that line the lower oesophagus).
- if you have been told by your doctor that you have an intolerance to some sugars (such as lactose).
- if you have had or have pain, swelling or numbness of the jaw or a “heavy jaw feeling” or loosening of a tooth.
- if you are under dental treatment or will undergo dental surgery, tell your dentist that you are being treated with Risedronate sodium.

Your doctor will advise you on what to do when taking Risedronate sodium if any of the above applies to you.

**Children and adolescents**

Risedronate sodium is not recommended for use in children below age 18 due to insufficient data on safety and efficacy.

**Other medicines and Risedronate sodium**

Medicinal products containing one of the following lessen the effect of Risedronate sodium if taken at the same time:
- calcium
- magnesium
- aluminium (for example some indigestion mixtures)
- iron.

Take these medicines at least 30 minutes after your Risedronate sodium tablet.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

**Risedronate sodium with food and drink**

It is very important that you do NOT take your Risedronate sodium tablet with food or drinks (other than plain water) so that it can work properly. In particular do not take this medicine at the same time as dairy products (such as milk) as they contain calcium (see section 2, “Other medicines and Risedronate sodium”).

Take food and drinks (other than plain water) at least 30 minutes after your Risedronate sodium tablet.

**Pregnancy and breast-feeding**

Do not take Risedronate sodium if you may be pregnant, are pregnant or planning to become pregnant (see section 2, “Do not take Risedronate sodium”). The potential risk associated with the use of Risedronate sodium in pregnant women is unknown.

Do not take Risedronate sodium if you are breast-feeding (see section 2, “Do not take Risedronate sodium”). Risedronate sodium should only be used to treat postmenopausal women and men.

**Driving and using machines**

Risedronate sodium is not known to affect your ability to drive and use machines.

**Risedronate sodium 35 mg film-coated tablets contain lactose**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
3. **How to take Risedronate sodium**

**Dosage**
Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

**Recommended dose:**
Take one Risedronate sodium tablet (35 mg of risedronate sodium) once a week. Choose one day of the week that best fits your schedule. Every week, take the Risedronate sodium tablet on your chosen day.

For your convenience, so that you take your tablet on the right day every week, there are printed boxes/spaces on the carton. Please mark the day of the week you have chosen to take your Risedronate sodium tablet.

**When to take the Risedronate sodium tablet**
Take your Risedronate sodium tablet at least 30 minutes before the first food, drink (other than plain water) or other medicine of the day.

**How to take the Risedronate sodium tablet**
- Take the tablet whilst you are in an upright position (you may sit or stand) to avoid heartburn.
- Swallow it with at least one glass (120 ml) of plain water.
- Swallow it whole. Do not suck or chew it.
- Do not lie down for 30 minutes after taking your tablet.

Your doctor will tell you if you need calcium and vitamin supplements, if you are not getting enough from your diet.

**If you take more Risedronate sodium than you should**
If you or somebody else has accidentally taken more Risedronate sodium tablets than prescribed, drink one full glass of milk and seek medical attention.

**If you forget to take Risedronate sodium**
If you have forgotten to take your tablet on your chosen day, take it on the day you remember. Return to taking one tablet once a week on the day the tablet is normally taken.

Do not take a double dose to make up for a forgotten dose.

**If you stop taking Risedronate sodium**
If you stop treatment you may begin to lose bone mass. Please talk to your doctor before you consider stopping treatment.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. **Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Stop taking Risedronate sodium and contact a doctor immediately** if you experience any of the following:
- Symptoms of a severe allergic reaction, such as:
  - Swelling of the face, tongue or throat
  - Difficulties in swallowing
  - Hives and difficulties in breathing
- Severe skin reactions that can include blistering of the skin.
Tell your doctor promptly if you experience the following side effects:

- Eye inflammation, usually with pain, redness and light sensitivity.
- Bone necrosis of the jaw (osteonecrosis) associated with delayed healing and infection, often following tooth extraction (see section 2, “Warnings and precautions”).
- Symptoms from oesophagus such as pain when you swallow, difficulties in swallowing, chest pain or new or worsened heartburn.

However in clinical studies the other side effects that were observed were usually mild and did not cause the patient to stop taking their tablets.

The side effects are stated according to the frequency they occur. The following convention has been used:

- Very common: affects more than 1 user in 10
- Common: affects 1 to 10 users in 100
- Uncommon: affects 1 to 10 users in 1,000
- Rare: affects 1 to 10 users in 10,000
- Very rare: affects less than 1 user in 10,000
- Not known: frequency cannot be estimated from the available data

### Common side effects

- Indigestion, feeling sick, stomach ache, stomach cramps or discomfort, constipation, feelings of fullness, bloating, diarrhoea.
- Pain in your bones, muscles or joints.
- Headache.

### Uncommon side effects

- Inflammation or ulcer of the oesophagus (the tube that connects your mouth with your stomach) causing difficulty and pain in swallowing (see also section 2, “Warnings and precautions”), inflammation of the stomach and duodenum (bowel draining the stomach).
- Inflammation of the coloured part of the eye (iris) (red painful eyes with a possible change in vision).

### Rare side effects

- Inflammation of the tongue (red swollen, possibly painful), narrowing of the oesophagus (the tube that connects your mouth with your stomach).
- Abnormal liver tests have been reported. These can only be diagnosed from a blood test.

### During postmarketing experience, the following side effects have been reported:

- Very rare: Talk to your doctor if you have ear pain, discharge from the ear, and/or an ear infection. These could be signs of bone damage in the ear.
- Frequency unknown:
  - Hair loss
  - Liver disorders, some cases were severe
  - Inflammation of small blood vessels mainly affecting the skin (leukocytoclastic vasculitis)

Rarely, at the beginning of treatment, a patient’s blood calcium and phosphate levels may fall. These changes are usually small and cause no symptoms.

Unusual fracture of the thigh bone particularly in patients on long-term treatment for osteoporosis may occur rarely. Contact your doctor if you experience pain, weakness or discomfort in your thigh, hip or groin as this may be an early indication of a possible fracture of the thigh bone.

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

### 5. How to store Risedronate sodium
- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the label, carton and blister after EXP. The expiry date refers to the last day of that month.
- This medicinal product does not require any special storage conditions.

Do not throw away any medicine via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Risedronate sodium 35 mg film-coated tablets contain

- The active substance is risedronate sodium (amorphous). Each tablet contains 35 mg risedronate sodium, equivalent to 32.48 mg risedronic acid.
- The other ingredients are: magnesium stearate, crospovidone, lactose monohydrate, microcrystalline cellulose, hypromellose (E464), colloidal anhydrous silica, hydroxypropylcellulose (E463), macrogol 400, macrogol 8000, titanium dioxide (E171), iron oxide yellow (E172), iron oxide red (E172)

What Risedronate sodium 35 mg film-coated tablets look like and contents of the pack

Film-coated tablet.
Orange 9.0 mm round, biconvex, film-coated tablet.

Pack sizes:
Blister packs: 2, 4, 8 and 12 film-coated tablets.
Tablet containers: 40 and 50 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Actavis Group PTC ehf
Reykjavikurvegi 76-78
220 Hafnarfjordur
Iceland

Manufacturer
Actavis hf.
Reykjavikurvegur 76-78
IS-220 Hafnarfjörður
Iceland

This leaflet was last revised in December 2015.