

Package leaflet: Information for the user
Risebon, 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. See section 4.

What is in this leaflet

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

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1. What Risebon is and what it is used for

Risebon 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.

The treatment of osteoporosis in **postmenopausal women**, even if osteoporosis is severe. It reduces the risk of spinal and hip fractures.

Treatment of osteoporosis in men at high risk of fractures.

2. What you need to know before you take Risebon

Do not take Risebon:

- 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 Risebon

- 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 Barrett'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 Risebon

Your doctor will advise you on what to do when taking Risebon if you have any of the above.

Children and adolescents

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

Other medicines and Risebon

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

Medicines containing one of the following, lessen the effect of Risebon if taken at the same time

- calcium
- magnesium
- aluminium (for example some indigestion mixtures)
- iron.

Take these medicines at least 30 minutes after your Risebon tablet.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Risebon with food and drink

It is very important that you do NOT take your Risebon 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, "Taking other medicines").

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

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Do NOT take Risebon if you may be pregnant, are pregnant or planning to become pregnant (see section 2, "Do not take Risebon"). The potential risk associated with the use of risedronate sodium (active substance in Risebon) in pregnant women is unknown.

Do NOT take Risebon if you are breast-feeding (see section 2, "Do not take Risebon")

Driving and using machines

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

Risebon contains lactose monohydrate

This medicine contains 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.

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3. How to take Risebon

Always take this medicine exactly as your doctor has told you. You should check with your doctor if you are not sure.

Usual dose:

Take ONE Risebon tablet (35 mg of risedronate sodium) once a week.

Choose one day of the week that best fits your schedule. Every week, take the Risebon tablet on your chosen day.

For your convenience, so that you take your tablet on the right day every week, there is a feature included with the Risebon pack:

There are boxes/spaces on the back of the cardboard carton. Please mark the day of the week you have chosen to take your Risebon tablet. Also, write in the dates you will take the tablet.

Take your Risebon tablet at least 30 minutes before the first food, drink (other than plain water) or other medicine of the day.

- 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 taking enough from your diet. Your diet should contain calcium and vitamin D (e.g. dairy products and fish).

If you take more Risebon than you should

No specific information is available on the treatment of overdose with risedronate sodium.

Decreases in serum calcium following substantial overdose may be expected. Signs and symptoms of hypocalcaemia may also occur in some of these patients.

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

If you forget to take Risebon

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 a forgotten tablet. If you have any further questions on the use of this product, ask your doctor.

If you stop taking Risebon

If you stop treatment you may begin to lose bone mass. Do not stop taking Risebon without consultation with your doctor even if feel better. Your doctor will inform you about duration of treatment with Risebon.

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

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4. Possible side effects

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

Stop taking Risebon and contact a doctor immediately if you experience any of the following:

- Symptoms characteristics of severe tissue swelling (angioedema reaction)
 - Swelling of face, tongue or throat
 - Difficulties in swallowing

- Hives and difficulties in breathing
- Severe skin reactions involving blisters under 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.

These reactions have been reported very rarely (less than 1 in 10,000 patients).

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.

Common side effects (1 to 10 users in 100)

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

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Uncommon side effects (1 to 10 users in 1,000)

- 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, "Take special care and talk to your doctor before you start taking Risebon"), 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 (1 to 10 users in 10,000)

- 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.

Very rare side effects

- 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.

During post-marketing experience, the following have been reported (unknown frequency):

- Hair loss;
- Liver disorders, some cases were severe;
- Hypersensitivity and skin reactions, including swelling of the face, mouth, tongue and/or neck (angioedema), skin rash and blistering, some severe life-threatening the skin and mucous membranes changes and inflammation of small blood vessels.

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.

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.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

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

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Risebon

Keep this medicine out of the sight and reach of children.

Store below 25°C.

Do not use this medicine after the expiry date which is stated on the pack after EXP. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Risebon contains

- The active substance is risedronate sodium. Each tablet contains 35 mg risedronate sodium, equivalent to 32.5 mg risedronic acid.
- The other ingredients are:

Tablet core: lactose monohydrate, cellulose microcrystalline, crospovidone, magnesium stearate.

Film coating: yellow iron oxide (E 172), red iron oxide (E 172), hypromellose, hydroxypropylcellulose, silica, colloidal anhydrous, titanium dioxide (E171), macrogol 400, macrogol 8000.

What Risebon looks like and contents of the pack

Risebon, 35 mg film-coated tablets are biconvex, pale orange coloured round tablet. The tablets are supplied in blister packs 2, 4 and 12 tablets. Not all pack sizes may be marketed.

Manufacturer

Manufacturer of dosage form and packaging of the medicinal product:

Pharmaceutical Works Adamed Pharma Joint Stock Company
33 Szkolna St., 95-054 Ksawerów, Poland

Manufacturer responsible for batch release:

Pharmaceutical Works Polfa in Pabianice Joint-Stock Co.
5 Marszałka J. Piłsudskiego Str.
95-200 Pabianice, Poland

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