

Package leaflet: Information for the user

Risedronate Bluefish Once a Week 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 or nurse.
- 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 or nurse. This includes any possible side effects not listed in this leaflet, See section 4.

What is in this leaflet:

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

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

What Risedronate Bluefish is

Risedronate Bluefish 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 Bluefish is used for

Risedronate Bluefish is used to treat osteoporosis in women after menopause and in this way reduces the risk of spinal and hip fractures.

Risedronate Bluefish is used for treatment of osteoporosis in men with high risk of fractures.

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

Do not take Risedronate Bluefish

- 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 or nurse before taking Risedronate Bluefish

- if you are unable to sit or stand upright for at least 30 minutes.
- if you have abnormal bone or mineral metabolism (for example vitamin D deficiency, parathyroid hormone abnormalities) which can lead to a low blood calcium level.
- if you had problems in the past with your oesophagus (the tube that takes food from your mouth to 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 had pain or swelling in your gums and/or jaw, numbed jaw, if your jaw feels heavy or if you have lost a tooth.
- if you are under dental treatment or have to undergo dental surgery, tell your dentist that you are taking Risedronate Bluefish.

If any of the above situations apply to you, please talk to your doctor before you take this medicine.

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 Bluefish

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

Medicinal products which contain one or more of the below mentioned minerals reduce the effect of Risedronate Bluefish if they are taken at the same time:

- calcium
- magnesium
- aluminium
- iron

These medicinal products should be taken at least 30 minutes after taking Risedronate Bluefish.

Risedronate Bluefish 35 mg may be used together with oestrogen supplementation (in women).

Risedronate Bluefish with food and drink and alcohol

It is very important that you do **NOT** take your Risedronate Bluefish tablet with food or drinks (other than plain water). It is especially important that this medicinal product is not taken at the same time as dairy produce (such as milk) because they contain calcium (see section 2 "Taking other medicines").

Food, drinks (except water) and other medicinal products should NOT be consumed for at least 30 minutes after taking Risedronate Bluefish.

Pregnancy and breast-feeding and fertility

Ask your doctor or pharmacist for advice before taking any medicine.

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

Do not take Risedronate Bluefish if you are breast feeding (see section 2 “Do not take Risedronate Bluefish”).

In women, Risedronate Bluefish should only be used after the menopause.

Driving and using machines

Risedronate Bluefish is not known to affect your ability to drive or use machines.

Risedronate Bluefish 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.

Risedronate Bluefish contains sodium

Risedronate Bluefish contains less than 1 mmol sodium (23 mg) per 35mg tablets, that is to say essentially ‘sodium-free’.

3. How to take Risedronate Bluefish

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

The recommended dose is one Risedronate Bluefish (35 mg risedronate sodium) once a week.

Choose one day of the week that fits you the best. Take one Risedronate Bluefish tablet every week on this weekday.

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

When to take your Risedronate Bluefish tablet:

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

How to take your Risedronate Bluefish tablet:

- Take the tablet whilst you are in an upright position (you may sit or stand). This prevents heartburn (burning feeling in the throat).
- Swallow the tablet with at least a glass (120 ml) of plain water. It is very important that you do NOT take your Risedronate Bluefish with food or drinks (other than plain water) so it can work properly.
- Swallow the tablet whole. Do not suck or chew the tablet.

- Do not lie down for 30 minutes after taking the tablet.

Your doctor will tell you if you need to take extra calcium and D-vitamin. It can be necessary if you do not get enough from your daily diet.

If you take more Risedronate Bluefish than you should

If you or somebody else has accidentally taken a large number of tablets, drink a full glass of milk and seek medical attention. Overdose causes a decrease in the levels of calcium in your body, the symptoms of which include sudden, painful, involuntary contractions usually involving the muscles of the abdomen.

If you forget to take Risedronate Bluefish

If you have forgotten to take your tablet, just take your tablet on the day you remember. Return to taking one tablet once a week, as originally scheduled on your chosen day.

Do not take a double dose to make up for a forgotten tablet (if you have forgotten to take a tablet for a week or more).

If you stop taking Risedronate Bluefish

Osteoporosis therapy is usually required for long periods. Please talk to your doctor before you consider stopping treatment. Stopping treatment will result in no beneficial effects of your therapy, and you may begin to lose bone strength again.

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

4. Possible side effects

Like all medicines, Risedronate Bluefish can cause side effects, although not everybody gets them.

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

Symptoms of a severe allergic reaction such as:

- Swelling of 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, "Take special care and talk to your doctor before you start taking Risedronate Bluefish").
- Symptoms from oesophagus such as pain when you swallow, difficulties in swallowing, chest pain or new or worsened heartburn.

Other side effects were observed were usually mild and did not cause the patients to stop taking their tablets:

Common side effects (less than 1 in 10 but more than 1 in 100 patients):

Constipation, feeling sick (dyspepsia), indigestion, stomach ache, stomach cramps or discomfort, bloating.

Pain in your bones, muscles or joints.

Headache.

Uncommon side effects (less than 1 in 100 but more than 1 in 1,000 patients):

Inflammation or ulcer of the oesophagus (the tube that connects your mouth with your stomach) causing difficulty and pain in swallowing. Inflammation or ulcer of the stomach and the duodenum (bowel draining the stomach).

Inflammation of the coloured part of the eye (iris) (red painful eyes with possible change in vision).

Rare side effects (less than 1 in 1,000 patients):

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.

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.

Very rare (less than 1 in 10,000 patients)

- 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.

Unknown frequency:

Osteonecrosis (death of bone tissue) in the jaw. Allergic reactions such as urticaria (skin rash), swelling of the face, lips, tongue and/or neck, difficulty in swallowing or breathing. Severe skin reactions including vesiculation (blistering) under the skin. Eye inflammation.

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

- Hair loss
- Liver disorders, some cases were severe
- Small blood vessel inflammation and destruction

In rare cases the patients calcium and phosphate levels can be reduced in the beginning of the treatment. These changes are most often minor and does not give any 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. **How to store Risedronate Bluefish**

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

This medicinal product does not require any special storage conditions.

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

Do not throw away any medicines 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 Bluefish 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: Starch, pregelatinised (maize); Cellulose, microcrystalline; Crospovidone; Magnesium stearate.
Film coating: Hypromellose, Lactose monohydrate, Titanium dioxide (E171), Macrogol 4000.

What Risedronate Bluefish looks like and contents of the pack

Risedronate Bluefish are white round biconvex film-coated tablets with diameter of 11.2 mm, 5.0 mm in thickness and embossed with “35” on one the side.

Risedronate Bluefish is available in Opaque PVC/PE/PVDC/Aluminium blisters of 4 & 12 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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This medicinal product is authorised in the Member States of the EEA under the following names:

Name of the Member State	Name of the medicinal product
Austria	Risedronsäure Bluefish einmal wöchentlich 35 mg Filmtabletten
France	Risedronate Bluefish 35 mg comprimés peliculés
Germany	Risedronat Bluefish 35 mg einmal wöchentlich Filmtabletten
Ireland	Risedronate Bluefish Once a week 35 mg film-coated tablets
Portugal	Risedronato de Sódio Bluefish 35 mg comprimidos revestidos por película
Sweden (RMS)	Risedronate Bluefish 35 mg Filmdragerade tabletter
Iceland	Risedronate Bluefish 35 mg filmuhúðaðar töflur

This leaflet was last revised in