

PACKAGE LEAFLET: INFORMATION FOR THE USER

Risedronate 30 mg film-coated tablets

Risedronate sodium

Read all of this leaflet carefully before you start taking this medicine.

- 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. 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 or pharmacist.

In this leaflet:

1. What Risedronate is and what it is used for
2. Before you take Risedronate
3. How to take Risedronate
4. Possible side effects
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1. WHAT RISEDRONATE IS AND WHAT IT IS USED FOR

What Risedronate is

Risedronate 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.

Paget's disease occurs when this process, called remodeling, happens too quickly and in a disordered way. The new bone that is produced is weaker than normal and the affected bones may become enlarged, painful and may fracture. Risedronate changes the bone remodeling process back to normal, returning the strength to the bone structure.

What Risedronate is used for

Treatment of Paget's disease of the bone (osteitis deformans).

2. BEFORE YOU TAKE RISEDRONATE

Do not take Risedronate

- if you are **allergic** (hypersensitive) to risedronate sodium or any of the other ingredients of Risedronate (see section 6 "What Risedronate contains").
- 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 are planning to become pregnant.
- if you are **breast-feeding**.
- if you have **severe kidney problems**.

Take special care and talk to your doctor BEFORE you start taking Risedronate

- 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 Risedronate.

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

Children

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

Taking other medicines

Medicines containing one of the following lessen the effect of Risedronate if taken at the same time:

calcium
magnesium
aluminium (for example some indigestion mixtures)
iron

Take these medicines at least 30 minutes after taking Risedronate.

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

Taking Risedronate with food and drink

It is very important that you do NOT take your Risedronate 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 Risedronate tablet.

Pregnancy and breast-feeding

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

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

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

Driving and using machines

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

Important information about some of the ingredients of Risedronate

Risedronate contains a small amount of 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 (see section 2, "Take special care and talk to your doctor before you start taking Risedronate").

3. HOW TO TAKE RISEDRONATE

Dosage

Always take Risedronate exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Usual dose

Take ONE Risedronate (30 mg risedronate sodium) once a day.

The recommended treatment duration is usually 2 months

When to take your Risedronate tablet:

IT IS BEST to take your tablet at least 30 minutes before the first food, drink (other than plain water) or other medicine of the day.

If in particular instance you are unable to take your Risedronate tablet at this time, you may take it on an empty stomach, at the same time every day, in one of the following ways:

EITHER:

Between meals: at least 2 hours after your last food, drink (other than plain water) or other medicine.

Do not eat or drink (other than plain water) for 2 hours after taking the tablet.

OR:

In the evening: at least 2 hours after your last food, drink (other than plain water) or other medicine of the day. Risedronate should be taken at least 30 minutes before going to bed.

How to take your Risedronate 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 the tablet.

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

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

If you take more Risedronate than you should

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

If you forget to take Risedronate

If you have forgotten to take your tablet at your regular time, you can take it at next possible time according to the instruction above before (i.e. breakfast, between meals, or in the evening)

Do not take two tablets in one day to make up for the tablet you missed.

If you stop taking Risedronate

Please talk to your doctor if you consider stopping treatment before end of prescribed duration.

4. POSSIBLE SIDE EFFECTS

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

Stop taking Risedronate 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, "Take special care and talk to your doctor before you start taking Risedronate").

Symptoms from oesophagus such as pain when you swallow, difficulties in swallowing, chest pain or new/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.

Common side effects (affects 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.

Uncommon side effects (affects 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 Risedronate"), 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 (affects 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.

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.

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

Allergic reactions of the skin such as urticaria (hives), 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; inflammation of small blood vessels, characterised by palpable red spots on the skin (leukocytoclastic vasculitis); a serious illness called Stevens Johnson syndrome (SJS) with blistering of the skin, mouth, eyes and other moist body surfaces (genitals); a severe illness called toxic epidermal necrolysis (TEN) which causes a red rash over many parts of the body and/or loss of the outer layer of skin.

Hair loss. Allergic reactions (hypersensitivity). Serious liver disorders, mainly if you are treated with other medicinal products known to cause liver problems. Inflammation of the eye which causes pain and redness.

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.

The additional following adverse events has also been observed in a clinical study in patients with Paget's disease: vision difficulties, breathing difficulties, coughing, inflammation of the large intestine, surface of the eye damage, cramps, dizziness, dryness of the eye, flu-like symptoms, muscle weakness, abnormal growth of cells, a frequent need to pass water at night, unusual lumps or swellings, chest pain, rash, runny nose, ringing in the ears and weight loss.

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nose, ringing in the ears and weight loss.

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.

5. HOW TO STORE RISEDRONATE

Keep out of the reach and sight of children.

This medicinal product does not require any special storage conditions.

Do not use Risedronate after the expiry date which is stated on the carton. 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. FURTHER INFORMATION

What Risedronate contains

- The active substance is Risedronate sodium. Each tablet contains 30 mg risedronate sodium, equivalent to 27.8 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 looks like and contents of the pack

Risedronate are white round biconvex film-coated tablets with diameter of 11.2 mm, 4.5 mm in thickness and embossed with “30” on one side. It is supplied in blister packs of 14, 28 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Aspire Pharma Limited
Bellamy House,
Winton Road,
Petersfield,
Hampshire,
GU32 3HA
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Manufacturer

Pharmathen SA
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15351 Pallini
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This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium RISEDREENOS 30 mg
Cyprus Risepallin 30 mg
Denmark Risepallin 30 mg
Germany Acara 30 mg Filmtabletten
Ireland Risedronate 30 mg Film-coated tablets
Italy Risedronato Germed 30 mg compresse rivestite con film
Luxembourg RISEDREENOS 30 mg
United Kingdom Risedronate sodium 30 mg film-coated tablets

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