

# PACKAGE LEAFLET: INFORMATION FOR THE USER

## Risedronate 5 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.

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 is more likely to occur in women who have reached the menopause early and also in patients treated long-term with steroids.

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 is used for

The treatment of osteoporosis

in **postmenopausal women**

The prevention of osteoporosis

in **women with an increased risk of osteoporosis** (including low bone mass, early menopause or a family history of osteoporosis).

in **postmenopausal women** who have been on **high doses of steroid drugs for a long time**. It maintains or increases bone mass.

## 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 use 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"). J"). 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 and 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 (5 mg risedronate sodium) once a day.

#### **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 the next possible time according to the instruction above (i.e. before 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**

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

### 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.

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 5 mg risedronate sodium, equivalent to 4.64 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 6.1 mm and 2.6 mm in thickness. It is supplied in blister packs containing 14, 28, 84, 98 tablets.

Not all pack sizes may be marketed.

### Marketing Authorisation Holder

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

### Manufacturer

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

Belgium RISEDREENOS 5 mg  
Cyprus Risepallin 5 mg  
Denmark Risepallin 5 mg  
Germany Acara 5 mg Filmtabletten  
Ireland Risedronate 5 mg Film-coated tablets  
Italy Risedronato Germed 5 mg compresse rivestite con film  
Luxembourg RISEDREENOS 5 mg  
United Kingdom Risedronate sodium 5 mg film-coated tablets

**This leaflet was last revised in 01/2013.**