

**Package leaflet: Information for the user**  
**RISEBONE 75 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 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 RISEBONE is and what it is used for
2. What you need to know before you take RISEBONE
3. How to take RISEBONE
4. Possible side effects
5. How to store RISEBONE
6. Contents of the pack and other information.

**1. What RISEBONE is and what it is used for**

**What RISEBONE is**

RISEBONE 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.

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 RISEBONE is used for**

The treatment of osteoporosis in postmenopausal women.

**2. What you need to know before you take RISEBONE**

**Do not take RISEBONE**

- 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 RISEBONE

- 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 had or have pain, swelling or numbness of the jaw or a “heavy jaw feeling” or loosening of a tooth.
- if you are undergoing dental treatment or will undergo dental surgery, tell your dentist that you are being treated with RISEBONE.

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

### **Children and adolescents**

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

### **Other medicines and RISEBONE**

Please 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 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 RISEBONE.

### **RISEBONE with food and drink**

It is very important that you do NOT take your medicine 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 RISEBONE”).

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

### **Pregnancy and breast-feeding**

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

Do NOT take RISEBONE if you are breast-feeding (see section 2, “Do not take RISEBONE”).

RISEBONE should only be used to treat postmenopausal women.

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

### **Driving and using machines**

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

## **3. How to take RISEBONE**

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:

RISEBONE tablets should be taken on the SAME two consecutive dates each month, e.g. on the 1st and 2nd of the month or the 15th and 16th. Choose TWO dates in a row that best fit your schedule to take your RISEBONE.

Take ONE RISEBONE tablet in the morning of your first chosen date. Take the SECOND tablet in the morning of the following day.

Repeat every month keeping the same two consecutive dates. To help you remember when to take your tablets next, you can mark your calendar ahead of time with a pen or stickers. You can write down the date in the space provided at the back of the box.

#### When to take the RISEBONE tablet

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

#### How to take the RISEBONE 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**. Do not take your tablet with mineral water or drinks other than plain water. Swallow it whole. Do not suck or chew your tablet.
- **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 RISEBONE than you should

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

#### If you forget to take RISEBONE

You forgot	When	What to do
1st and 2nd tablets	Next monthly dose is more than 7 days ahead	Take 1st tablet the next morning and 2nd tablet the morning of the following day
	Next monthly dose is within 7 days	Do not take the tablets you have forgotten
2nd tablet only	Next monthly dose is more than 7 days ahead	Take 2nd tablet the next morning
	Next monthly dose is within 7 days	Do not take the tablet you have forgotten
The next month, take your tablets again as usual		

In any case:

- If you miss your dose of RISEBONE tablet in the morning, do NOT take it later in the day.
- **Do NOT take three tablets within the same week.**

#### If you stop taking RISEBONE

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 the 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 RISEBONE and contact a doctor immediately** if you experience any of the following:

- Symptoms of a severe allergic reaction such as
  - swelling of face, lips, tongue, throat and/or neck
  - difficulties in swallowing
  - hives, skin rash and difficulties in breathing
- Severe skin reactions such as

- blistering of the skin, mouth, eyes and other moist body surfaces (genitals) (Stevens Johnson syndrome).
- Palpable red spots on the skin (leukocytoclastic vasculitis)
- Red rash over many parts of the body and/or loss of the outer layer of skin (toxic epidermal necrolysis).

**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.

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.

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** (may affect up to 1 in 10 people)

Indigestion, feeling sick, being sick, stomach ache, stomach cramps or discomfort, constipation, feelings of fullness, bloating, diarrhoea.

Pain in your bones, muscles or joints.

Headache.

**Uncommon side effects** (may affect up to 1 in 100 people)

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).

Fever, flu-like symptoms.

**Rare side effects** (may affect up to 1 in 1,000 people)

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

- Hair loss.
- Liver disorders, some cases were severe.
- Inflammation of the small blood vessels.

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.

### **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 RISEBONE**

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 carton after EXP. The expiry date refers to the last day of that month.

Store below 30°C.

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 RISEBONE contains**

The active substance is risedronate sodium. Each tablet contains 75 mg risedronate sodium (equivalent to 69.6 mg risedronic acid).

The other ingredients are: cellulose, microcrystalline, crospovidone, magnesium stearate, titanium dioxide (E171), hypromellose, macrogol 6, talc000 and red iron oxide (E172).

##### **What RISEBONE looks like and contents of the pack**

The film-coated tablets are pinkish and marked. The tablets are available in blisters in pack sizes containing 2 tablets

##### **Marketing Authorisation Holder and manufacturer**

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**This leaflet was last revised in October 2014.**