

## Package leaflet: Information for the user

### Risedronate sodium 35mg Once a Week film-coated tablet 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.

#### What is in this leaflet

1. What Risedronate sodium 35mg Once a Week film-coated tablet is and what it is used for
2. What you need to know before you take Risedronate sodium 35mg Once a Week film-coated tablet
3. How to take Risedronate sodium 35mg Once a Week film-coated tablet
4. Possible side effects
5. How to store Risedronate sodium 35mg Once a Week film-coated tablet
6. Contents of the pack and other information

#### 1. What Risedronate sodium 35mg Once a Week film-coated tablets is and what it is used for

Risedronate Sodium belongs to a group of non-hormonal medicines called biphosphonates, which are used to treat bone diseases. Risedronate Sodium Tablets act directly on your bones, making them stronger, and reducing fracture risk.

The bone is a living tissue. Old bone is constantly removed from the skeleton and replaced by new bone.

Menopausal osteoporosis is a disease occurring in postmenopausal women where the bones become weaker, more fragile and more easily prone to break (causing fractures) after a fall or physical efforts.

Osteoporosis can also occur in men due to a number of causes, which include age and/or low levels of male hormone, testosterone.

The spine, the hip and the wrist are bones with a higher fracture risk, although any bone may be affected. Fractures related to osteoporosis may also cause back pain, height loss and changes in the spine curve. Many patients with osteoporosis have no symptoms and may not even be aware they have it.

What is Risedronate sodium used for.

Treatment of osteoporosis:

- In postmenopausal women, even in cases of serious osteoporosis. Reduces the vertebral and hip fractures risk.
- In men.

#### 2. What you need to know before you take Risedronate Sodium 35mg Once a week film-coated Tablets

##### Do not take Risedronate Sodium 35mg Once a week film-coated tablet

- if you are allergic to risedronate sodium or any of the other ingredients of this medicine (listed in section 6).
- if you were informed by your doctor that you show an alteration called hypocalcaemia (low blood calcium levels);
- if you think you are pregnant, if you are pregnant, or if you plan to get pregnant;
- if you are breast-feeding;

- if you have serious kidney problems.

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Risedronate Sodium Tablets

- If you are unable to remain seated or in the upright position for at least 30 minutes;
- If you show changes of bone and mineral metabolism (for instance vitamin D deficiency, changes in the parathyroid hormone, both leading to a decrease of blood calcium levels);
- 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 feel or have felt pain, swelling or jaw numbness or a feeling of "heavy jaw", or if you have loosening of a tooth;
- If you are undergoing dental treatment or if you are going to be submitted for dental surgery, you should inform your dentist that you are taking Risedronate Sodium Tablets.
- If you have been told by your doctor that you have an intolerance to some sugars (such as lactose)

Your doctor will tell you what to do when you are taking Risedronate Sodium Tablets if you experience any of the above mentioned problems.

### **Children**

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

### **Other medicines and Risedronate Sodium Tablets**

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

Few medicines are known to interfere with the effect of Risedronate Sodium Tablets.

Medicines containing one of the following substances may reduce the effect of Risedronate Sodium Tablets, if taken simultaneously:

- calcium;
- magnesium;
- aluminium (used in some medicinal products for indigestion);
- iron.

Take these medicines, at least, 30 minutes after your tablet of Risedronate Sodium Tablets.

### **Risedronate Sodium Tablets with food and drink**

It is very important that you DO NOT take Risedronate Sodium Tablets with food, other medicines or drinks (other than water), so that it may act properly. In particular, do not take this medicine at the same time as dairy products (such as milk) since they contain calcium (see section 2 "Other medicines and Risedronate Sodium Tablets").

You may eat or drink (other than water) after 30 minutes after taking your Risedronate Sodium 35mg Once a Week film coated tablet.

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

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

Risedronate Sodium Tablets should only be used to treat postmenopausal women and men.

### **Driving and using machines**

Risedronate Sodium Tablets has no known effects on the ability to drive vehicles or use machines.

**Risedronate Sodium Tablets contains lactose.**

If you have been told by your doctor that you have an intolerance to some sugars (such as lactose), contact your doctor before taking this medicinal product

**3. How to take Risedronate Sodium 35mg Once a Week film-coated Tablets**

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:

Take ONE tablet of Risedronate Sodium Tablets once a week.

Choose a day of the week which is more convenient for you and take the tablet always that same day each week.

When to take Risedronate Sodium Tablets

Take your Risedronate Sodium tablet at least 30 minutes before the first food, other medicines or drinks (other than water) of the day.

How to take Risedronate Sodium Tablets

- Take the tablet on a upright position (you may sit down or stand) to avoid heartburn;
- Swallow it with, at least, a glass of water (120 ml);
- Swallow it whole, without sucking or chewing it;
- Do not lie down for 30 minutes after taking the tablet.

Your doctor will tell you if you need to take supplemental calcium and vitamins if dietary intake is insufficient.

**If you take more Risedronate Sodium Tablets than you should**

If you have accidentally taken more Risedronate Sodium Tablets than you are prescribed, drink a full glass of milk.

**If you forget to take Risedronate Sodium Tablets**

If you forget to take Risedronate Sodium tablet at the due day, you should take the tablet on the very day you remember it.

You should then return to taking the tablet once a week on the day of the week that was initially chosen.

Do not take a double dose to make up for a forgotten tablet.

**If you stop taking Risedronate Sodium Tablets**

If you stop treatment you may start losing bone mass. Check with your doctor before you stop treatment.

If you have any further questions on the use of this 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 Risedronate Sodium Tablets 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, “Warnings and precautions”).
- Symptoms from oesophagus such as pain when you swallow, difficulties in swallowing, chest pain or new or 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 (may affect up to 1 in 10 people)

- Indigestion, feeling sick, stomach ache, stomach cramps or discomfort, constipation, feeling of fullness, bloating and diarrhoea.
- Pain in the bone, muscles or joints;
- Headache.

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

- inflammation or ulcer of the oesophagus (tube that connects the mouth to the stomach) causing difficulty or pain in swallowing (see also section 2 “**Warnings and precautions**”, inflammation of the stomach and duodenum (the part of the intestine which empties the stomach).
- inflammation of the coloured part of the eye (iris) (red painful eyes with a possible change in vision).

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

- inflammation of the tongue (red, swollen and possibly painful), narrowing of the oesophagus (tube that connects the mouth to the 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

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.

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 thighs, hip or groin as this may be an early indication of a possible fracture of the thigh bone.

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

## **5. How to store Risedronate Sodium 35mg Once a Week film-coated Tablets**

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date stated on the carton, after EXP. The expiry date refers to the last day of that month.
- This medicine does not require any special storage conditions.

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 Sodium Tablet contains**

- The active substance is risedronate sodium. Each tablet of Risedronate Sodium contains 35 mg of risedronate sodium, equivalent to 32.5 mg of risedronic acid.
- Other components are:  
Tablet core: lactose monohydrate, microcrystalline cellulose, crospovidone, colloidal anhydrous silica and magnesium stearate.  
Coating: Opadry orange 20C53825, hypromellose 6 cp (E464), titanium dioxide (E171), macrogol/polyethylene glycol 400, hydroxypropyl cellulose (E463), hypromellose 15 cp (E464), macrogol/ polyethylene glycol 8000, ferric oxide yellow (E172), ferric oxide red (E172) and colloidal anhydrous silica (E551).

### **What Risedronate Sodium Tablets looks like and contents of the pack**

Risedronate Sodium Tablets are film-coated, round, light orange, with “R16” engraved on one side and plain on the other side.

Blisters in packs containing 1, 2, 4, 10, 12 or 16 tablets.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder:**

Ranbaxy Ireland Ltd, Spafield, Cork Road, Cashel, Co. Tipperary, Ireland.

### **Manufacturer**

Ranbaxy Ireland Ltd, Spafield, Cork Road, Cashel, Co. Tipperary, Ireland.

### **OR**

Terapia SA, Str Fabricii nr. 124, Cluj, Napoca, Romania

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

PT	Risedronato de Sódio Ranbaxy
ES	Risedronato Semanal Ranbaxy 35 mg Comprimidos recubiertos con película EFG
IT	Risedronato Ranbaxy
IE	Risedronate sodium 35mg Once a Week film-coated tablet
PL	RESORPATE
FR	RISEDRONATE RANBAXY 35 mg, comprimé pelliculé
RO	Osodens 35 mg, comprimate filmate

This leaflet was last revised in December 2014