PACKAGE LEAFLET

Package leaflet: Information for the patient

Risedronate Sodium Actavis one weekly 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.
- 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 Risedronate Sodium Actavis once weekly is and what it is used for

What Risedronate Sodium Actavis once weekly is
Risedronate Sodium Actavis once weekly 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 Sodium Actavis once weekly is used for
The treatment of osteoporosis
- in postmenopausal women, even if osteoporosis is severe. It reduces the risk of spinal and hip fractures.
- in men at high risk of fractures.

2. What you need to know before you take Risedronate Sodium Actavis once weekly

Do not take Risedronate Sodium Actavis once weekly:
- 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 Risedronate Sodium Actavis once weekly
- 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 or have had problems in the past with your oesophagus (the tube that connects your mouth with your stomach). For instance you may have or 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. This might be a symptom of osteonecrosis (death of bone tissue). Talk to your doctor if you suffer from cancer, receive chemotherapy, radiotherapy, corticosteroids or if your teeth are in bad condition as this is a risk factor.
- if you are under dental treatment or will undergo dental surgery, tell your dentist that you are being treated with Risedronate Sodium Actavis once weekly.

Your doctor will advise you on what to do when taking Risedronate Sodium Actavis once weekly if any of the above applies to you.

Children and adolescents
Risedronate Sodium Actavis once weekly is not recommended for use in children below age 18 due to insufficient data on safety and efficacy.

Other medicines and Risedronate Sodium Actavis once weekly
Medicinal products containing one of the following lessen the effect of Risedronate Sodium Actavis once weekly if taken at the same time:
- calcium
- magnesium
- aluminium (for example some indigestion mixtures)
- iron.

Take these medicines at least 30 minutes after your Risedronate Sodium Actavis once weekly tablet.

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

Risedronate Sodium Actavis once weekly with food and drink
It is very important that you do NOT take your Risedronate Sodium Actavis once weekly 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, "Other medicines and Risedronate Sodium Actavis once weekly ").
Take food and drinks (other than plain water) at least 30 minutes after your Risedronate Sodium Actavis once weekly tablet.

Pregnancy and breast-feeding
Do not take Risedronate Sodium Actavis once weekly if you may be pregnant, are pregnant or planning to become pregnant (see section 2, "Do not take Risedronate Sodium Actavis once weekly"). The potential risk associated with the use of risedronate sodium (active substance in Risedronate Sodium Actavis once weekly) in pregnant women is unknown.
Do not take Risedronate Sodium Actavis once weekly if you are breast-feeding (see section 2, "Do not take Risedronate Sodium Actavis once weekly ").
Risedronate Sodium Actavis once weekly should only be used to treat postmenopausal women and men.

Driving and using machines
Risedronate Sodium Actavis once weekly is not known to affect your ability to drive and use machines.

Risedronate Sodium Actavis once weekly 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.

3. How to take Risedronate Sodium Actavis once weekly

Dosage
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 Risedronate Sodium Actavis once weekly tablet (35 mg of risedronate sodium) once a week. Choose one day of the week that best fits your schedule. Every week, take the Risedronate Sodium Actavis once weekly tablet on your chosen day.

For your convenience, so that you take your tablet on the right day every week, there are printed boxes/spaces on the carton. Please mark the day of the week you have chosen to take your Risedronate Sodium Actavis once weekly tablet.

When to take the Risedronate Sodium Actavis once weekly tablet
Take your Risedronate Sodium Actavis once weekly tablet at least 30 minutes before the first food, drink (other than plain water) or other medicine of the day.

How to take the Risedronate Sodium Actavis once weekly 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 it.
- 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 Risedronate Sodium Actavis once weekly than you should
If you or somebody else has accidentally taken more Risedronate Sodium Actavis once weekly tablets than prescribed, drink one full glass of milk and seek medical attention or a hospital. A reduction in blood calcium may be expected in cases of overdosage. The signs and symptoms of very low blood calcium include tingling of fingers, toes and around the mouth, muscle spasm, seizures and possible life threatening conditions such as spasm of the vocal cords and irregular heart beat.

If you forget to take Risedronate Sodium Actavis once weekly
If you have forgotten to take your tablet on your chosen day, take it on the day you remember.
Return to taking one tablet once a week on the day the tablet is normally taken.

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

If you stop taking Risedronate Sodium Actavis once weekly
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 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 Actavis once weekly and contact a doctor immediately if you experience any of the following:
- Symptoms of severe allergic reactions 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, "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, 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).

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

Very rare side effects (may affect up to 1 in 10,000 people)
- 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.

Not known (frequency cannot be estimated from the available data)
- 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.

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. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6767836. 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 Sodium Actavis once weekly

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 package. 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 Sodium Actavis once weekly contains

- The active substance is 35 mg risedronate sodium (amorphous), equivalent to 32.48 mg risedronic acid.
- The other ingredients are:
  - *tablet core:* magnesium stearate, crospovidone, lactose monohydrate, microcrystalline cellulose;
  - *tablet film-coating:* hypromellose, colloidal silica, anhydrous, hydroxypropylcellulose, macrogol 400, macrogol 8000, titanium dioxide (E171), iron oxide yellow (E172), iron oxide red (E172)

What Risedronate Sodium Actavis once weekly looks like and contents of the pack

Film-coated tablet.
Orange 9.0 mm round, film-coated tablet.

Pack sizes:
Blister packs: 2, 4, 8 and 12 film-coated tablets.
Tablet containers: 4 and 12 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Accord Healthcare Ireland Ltd,
Euro House,
Euro Business Park,
Little Island,
Cork T45 K857,
Ireland

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