PACKAGE LEAFLET: INFORMATION FOR THE USER

Risedronate sodium 5 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 symptoms 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.
- The full name of the product is Risedronate sodium 5 mg film-coated tablets but within the leaflet it will be referred to as Risedronate sodium tablets.

What is in this leaflet

1. What Risedronate sodium tablets are and what they are used for
2. What you need to know before you take Risedronate sodium tablets
3. How to take Risedronate sodium tablets
4. Possible side effects
5. How to store Risedronate sodium tablets
6. Contents of the pack and other information

1. What Risedronate sodium tablets are and what they are used for

What Risedronate sodium tablets are
Risedronate sodium tablets belong 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.
It is more likely that early menopausal women and patients on long-term steroid treatment get osteoporosis.

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 tablets are 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 and a family history of osteoporosis)
- in postmenopausal women undergoing long-term steroid treatment at high doses. Bone mass is withheld or increased.

2. What you need to know before you take Risedronate sodium tablets

Do not take Risedronate sodium tablets
- if you are allergic (hypersensitive) to risedronate sodium or any of the other ingredients of Risedronate sodium tablets (see 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 tablets
- 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 ofa tooth.
- if you are under dental treatment or will undergo dental surgery, tell your dentist that you are being treated with Risedronate sodium tablets.
- if you have had problems with your ears and/or had long term ear infections.

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

Children and adolescents
Risedronate sodium tablets are not recommended for use in children below 18 years of age 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.

Medicinal products containing one of the following lessen the effect of Risedronate sodium tablets 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 tablet.

Risedronate sodium tablets with food and drink
It is very important that you do NOT take your Risedronate sodium 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 tablets”).
Take food and drinks (other than plain water) at least 30 minutes after your Risedronate sodium tablet.

Pregnancy and breast-feeding
Ask your doctor or pharmacist for advice before taking any medicine.

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 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”).

Driving and using machines
Risedronate sodium tablets are not known to affect your ability to drive and use machines.

Risedronate sodium tablets contain 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.

Information on sodium content

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Risedronate sodium tablets

Always take Risedronate sodium tablets 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 sodium tablet (5 mg of risedronate sodium) once a day.

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

If you are unable to take your Risedronate sodium 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: Risedronate sodium tablets should be taken at least 2 hours before and at least 2 hours after any food, medicinal product or drink (other than plain water).
- Or
  In the evening: Risedronate sodium tablets should be taken at least 2 hours after the last food, medicinal product or drink (other than plain water) of the day. Risedronate sodium should be taken at least 30 minutes before going to bed.

How to take the Risedronate sodium 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 tablets than you should
If you or somebody else has accidentally taken more Risedronate sodium tablets than prescribed, drink one full glass of milk and seek medical attention.

If you forget to take Risedronate sodium tablets
If you forget to take Risedronate sodium tablet at the usual time, you can take the tablet according to the instructions above (i.e. before breakfast, between meals or in the evening).

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

If you stop taking Risedronate sodium tablets
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 tablets 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, "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 1000 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.

Very rare (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.

During post marketing experience, the following side effects have been reported (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 (see details below).
Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard

or search for MHRA Yellow Card in Google Play or Apple App Store.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Risedronate sodium tablets

Keep this medicine out of the sight and reach of children.

Do not use Risedronate sodium tablets after the expiry date which is stated on the label, carton and blister after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

If the medicine becomes discoloured or show any signs of deterioration, seek the advice of your pharmacist.

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 tablets contain
- The active substance is risedronate sodium (amorphous). Each tablet contains 5 mg risedronate sodium, equivalent to 4.64 mg risedronic acid.
- The other ingredients are: magnesium stearate, crospovidone, lactose monohydrate, microcrystalline cellulose, hypromellose (E464), colloidal anhydrous silica, hydroxypropylcellulose (E463), macrogol 400, macrogol 8000, titanium dioxide (E171), iron oxide yellow (E172)

What Risedronate sodium tablets look like and contents of the pack
Risedronate sodium 5 mg Film-coated tablet is Yellow 8.5 mm round, biconvex, film-coated tablet.

Pack sizes:
Blister packs: 7, 14, 28, 56, 84 film-coated tablets
Tablet containers: 30 and 100 film-coated tablets

Not all pack sizes may be marketed.

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Torrent Pharma (UK) Ltd.
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