Package leaflet: Information for the patient

Risedronate Sodium Accord 30 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.
- The full name of this medicine is Risedronate Sodium Accord 30 mg film-coated tablets but within this leaflet it will be referred to as Risedronate Sodium Accord.

What is in this leaflet

1. What Risedronate Sodium Accord is and what it is used for

What Risedronate Sodium Accord is
Risedronate Sodium Accord 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.

Paget's disease occurs when this process, called remodeling, happens too quickly and in a disordered way. The new bone that is produced is weaker than normal and the affected bones may become enlarged, painful and may fracture. Risedronate Sodium Accord changes the bone remodeling process back to normal, returning the strength to the bone structure.

What Risedronate Sodium Accord is used for
Treatment of Paget's disease of the bone (osteitis deformans).

2. What you need to know before you take Risedronate Sodium Accord

Do not take Risedronate Sodium Accord
- 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 Accord

- 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.
- If you are under dental treatment or will undergo dental surgery, tell your dentist that you are being treated with Risedronate Sodium Accord**.**

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

Children and adolescents
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 Accord
Medicines containing one of the following lessen the effect of Risedronate Sodium Accord 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 Accord tablet.

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

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

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

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

Risedronate Sodium Accord **contains a small amount of lactose** (see section 2, "Warnings and precautions").

3. How to take Risedronate Sodium Accord

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 ONE Risedronate Sodium Accord tablet (30 mg of risedronate sodium) once a day. The recommended treatment duration is usually 2 months.

For your convenience, the days of the week are printed on the blister foil to help you remember to take your medicine.

WHEN to take the Risedronate Sodium Accord tablet
IT IS BEST to take your Risedronate Sodium Accord 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 Sodium Accord 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 Sodium Accord should be taken at least 30 minutes before going to bed.

HOW to take the Risedronate Sodium Accord 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 taking enough from your diet.

If you take more Risedronate Sodium Accord than you should
If you or somebody else has accidentally taken more Actonel tablets than prescribed, drink one full glass of milk and seek medical attention.

If you forget to take Risedronate Sodium Accord
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 a double dose to make up for a forgotten tablet.

If you stop taking Risedronate Sodium Accord
Please talk to your doctor if you consider stopping treatment before the end of prescribed duration.

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 Accord 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 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.

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 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.

The additional following adverse events has also been observed in a clinical study in patients with Paget's disease: vision difficulties, breathing difficulties, coughing, inflammation of the large intestine, surface of the eye damage, cramps, dizziness, dryness of the eye, flu-like symptoms, muscle weakness, abnormal growth of cells, a frequent need to pass water at night, unusual lumps or swellings, chest pain, rash, runny nose, ringing in the ears and weight loss.

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 6762517. 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 Accord

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 and blister 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 Accord contains
The active substance is risedronate sodium. Each tablet contains 30 mg risedronate sodium, equivalent to 27.8 mg risedronic acid.

The other ingredients are:
Tablet core: lactose monohydrate (see section 2), crospovidone, magnesium stearate and cellulose microcrystalline.

Film coating: hypromellose, macrogol, hydroxypropylcellulose, colloidal anhydrous silica and titanium dioxide [E171].

What Risedronate Sodium Accord looks like and contents of the pack
Risedronate Sodium Accord 30 mg film-coated tablets are oval white tablets with the letters "RSN" on one side and "30 mg" on the other side. The tablets are supplied in blister packs of 1x3, 1x14, 28 (2x14) tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder

Accord Healthcare Ireland Ltd,
Euro House,
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Little Island,
Cork T45 K857,
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Manufacturer:
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Balkanpharma-Dupnitsa AD,
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Bulgaria

This medicinal product is authorised in the Member States of the EEA under the following names:
Ireland: Risedronate Sodium Accord 30 mg film-coated tablets
United Kingdom: Risedronate Sodium Accord 30 mg film-coated tablets

This leaflet was last revised in: March 2020