Pharmacode position may change as per Supplier's m/c requirement &additional small pharma code may appear on the front / back panel

Risedronate sodium P1540245

Risedronate sodium P1540245

Package leaflet:
Information for the user

Risedronate sodium 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.

What is in this leaflet
The name of your medicine is Risedronate sodium 30 mg film-coated tablets (referred to as Risedronate tablets throughout this leaflet).

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

1. What Risedronate tablets is and what it is used for

What Risedronate tablets is
Risedronate tablets 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 tablets changes the bone remodeling process back to normal, returning the strength to the bone structure.

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

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

Do not take Risedronate tablets
- 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 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 of a tooth.
- If you are under dental treatment or will undergo dental surgery, tell your dentist that you are being treated with Risedronate tablets.

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

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

Other medicines and Risedronate tablets
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 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 tablets.

Risedronate tablets with food and drink
It is very important that you do NOT take your Risedronate tablets 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 tablets").

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

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

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

Do not take Risedronate tablets if you are breast-feeding (see section 2, "Do not take Risedronate tablets").

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

Risedronate tablets 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.

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

3. How to take Risedronate 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 Risedronate tablets (30 mg of risedronate sodium) once a day.
The recommended treatment duration is usually 2 months.

When to take the Risedronate tablets
It is best to take your Risedronate tablets 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 tablets 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 tablets should be taken at least 30 minutes before going to bed.

How to take the Risedronate tablets
- 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.

Black A/s: 210 x 360 mm

AUROBINDO Packaging Development	Product Name: Risedronate 30 mg	Component: Leaflet	Item Code: P1540245	Date & Time: 06.10.2025 & 9:15 AM
	Customer / Country: Milpharm_Unit 3	Version No.: 01	Reason Of Issue: Revision	Reviewed / Approved by
Team Leader: Ramesh P	Dimensions: 210 x 360 mm	No. of Colours : 01		
Initiator: Jaya Durga				
Artist: Vision Graphic Designers	Pharmacode: 40245			
Additional Information : Supersede item Code: P1525529				Sign / Date

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

If you forget to take Risedronate tablets
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 dose.

If you stop taking Risedronate tablets
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 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.

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: 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**:**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**:** 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.

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.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Risedronate Tablets

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 tablets contains
The active substance is risedronate sodium. Each film-coated tablet contains 30 mg risedronate sodium (equivalent to 27.8 mg risedronic acid).

The other ingredients are:
Tablet core: Lactose monohydrate, crospovidone, hydroxy propyl cellulose, magnesium stearate and cellulose microcrystalline.
Film coating: Hypromellose, titanium dioxide (E171), macrogol 400, hydroxy propyl cellulose.

What Risedronate tablets looks like and contents of the pack
Film-coated tablet.

White to off-white coloured, circular shaped film coated biconvex tablets debossed with 'L' on one side and '30' on the other side.

Transparent PVC / PE / PVdC / Aluminium blisters in a cardboard box, Packs of 14 or 28 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Milpharm Limited
1 Roundwood Avenue
Stockley Park, Uxbridge
UB11 1AF
United Kingdom

Manufacturer
APL Swift Services (Malta) Limited
HF26, Hal Far Industrial Estate, Hal Far
Birzebbugia, BBG 3000
Malta

or

Milpharm Limited
1 Roundwood Avenue
Stockley Park, Uxbridge
UB11 1AF
United Kingdom

This leaflet was last revised in 10/2025.

P1540245