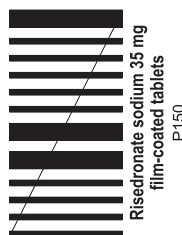


Pharmacode position may change as per Supplier's m/c requirement & additional small pharma code may appear on the front / back panel



PACKAGE LEAFLET: INFORMATION FOR THE USER

Risedronate sodium 35 mg film-coated tablets

risedronate sodium

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

The name of your medicine is Risedronate sodium 35 mg film-coated tablets (referred to as Risedronate tablets throughout this leaflet).

1. What Risedronate tablets is and what it is used for
2. Before you take Risedronate tablets
3. How to take Risedronate tablets
4. Possible side effects
5. How to store Risedronate tablets
6. Further 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.

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 tablets 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.

2. BEFORE YOU TAKE RISEDRONATE TABLETS

Do NOT take Risedronate tablets

- If you are allergic to risedronate sodium or any of the other ingredients of Risedronate tablets (see section 6, "What Risedronate tablets contains")
- 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.

Take special care and talk to your doctor BEFORE you start 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

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

Taking 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.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Taking 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, "Taking other medicines").

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

Pregnancy and breast-feeding

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").

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

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

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

Important information about some of the ingredients of Risedronate tablets

Risedronate tablets contains a small amount of lactose (see section 2, "Take special care and talk to your doctor before you start taking Risedronate tablets").

3. HOW TO TAKE RISEDRONATE TABLETS

Dosage

Always take Risedronate tablets exactly as your doctor has told you. You should check with your doctor if you are not sure.

Usual dose:

Take ONE Risedronate tablets (35 mg of risedronate sodium) once a week.

Choose one day of the week that best fits your schedule. Every week, take the Risedronate tablets on your chosen day.

For your convenience, so that you take your tablet on the right day every week, there is a feature included with the Risedronate tablets pack:

WHEN to take the Risedronate tablets

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

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.

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 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 two tablets in one day to make up for the tablet you missed.

If you STOP taking Risedronate 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 product, ask your doctor or pharmacist

4. POSSIBLE SIDE EFFECTS

Like all medicines, Risedronate tablets can cause side effects, although not everybody gets them.

Stop taking Risedronate Aurobindo 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, "Take special care and talk to your doctor before you start taking Risedronate tablets").
- 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 (less than 1 in 10 but more than 1 in 100 patients)

- 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 (less than 1 in 100 but more than 1 in 1,000 patients)

- 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, "Take special care and talk to your doctor before you start taking Risedronate tablets"), 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 (less than 1 in 1,000 patients)

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

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE RISEDRONATE TABLETS

Keep out of the reach and sight 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 medicinal product does not require any special storage conditions.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Risedronate tablets contains

The active substance is risedronate sodium. Each film-coated tablet contains 35 mg risedronate sodium (equivalent to 32.4 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, iron oxide yellow (E172), macrogol 8000, iron oxide red (E172) and silica colloidal anhydrous.

What Risedronate tablets looks like and contents of the pack

Film-coated tablet.

Light orange coloured, circular shaped film coated biconvex tablets debossed with 'F27' on one side and plain on the other side. Transparent PVC / PE / PVdC / Aluminium blisters in a cardboard box, Packs 1, 2, 4, 10, 12 or 16 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Milpharm Limited
Ares, Odyssey Business Park
West End Road
South Ruislip HA4 6QD
United Kingdom

Manufacturer

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

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

France	RISEDRONATE AUROBINDO 35 mg comprimé pelliculé
Germany	Risedronat Aurobindo einmal wöchentlich 35 mg Filmtabletten
Ireland	Risedronate Aurobindo Once a Week 35 mg film-coated tablets
Italy	Risedronato Aurobindo 35 mg compresse rivestite con film
Malta	Risedronate Aurobindo Once a Week 35 mg film-coated tablets
Romania	Risedronat Aurobindo 35 mg comprimate filmate
Spain	Risedronat Semanal Aurobindo 35 mg comprimidos recubiertos con película EFG
The Netherlands	Natriumrisedronaat Aurobindo Wekelijks 35 mg, filmomhulde tabletten
United Kingdom	Risedronate sodium 35mg film-coated tablets

This leaflet was last approved in 11/2012.