

## **Package leaflet: information for the user**

### **Risedronate Aurobindo 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. 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 or nurse. This includes any possible side effects not listed in this leaflet. See section 4

#### **What is in this leaflet:**

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

#### **1. What Risedronate Aurobindo is and what it is used for**

##### **What Risedronate Aurobindo is**

Risedronate Aurobindo 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 is more likely to occur in women who have reached the menopause early and also in patients treated long-term with steroids.

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 Aurobindo is 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 or a family history of osteoporosis).
- in **postmenopausal women** who have been on **high doses of steroid drugs for a long time**. It maintains or increases bone mass.

#### **2. What you need to know before you take Risedronate Aurobindo**

##### **Do not take Risedronate Aurobindo**

- 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 Aurobindo

- 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 Aurobindo.

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

### **Children and adolescents**

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

### **Other medicines and Risedronate Aurobindo**

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 Aurobindo 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 Aurobindo tablet.

### **Risedronate Aurobindo with food and drink**

It is very important that you do not take your Risedronate Aurobindo 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 Aurobindo”).

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

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

Do NOT take Risedronate Aurobindo if you are breast-feeding (see section 2, “Do not take Risedronate Aurobindo”).

### **Driving and using machines**

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

### **Risedronate Aurobindo contains lactose.**

Risedronate Aurobindo contains a small amount of lactose (see section 2, “Warnings and precautions”). 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 Aurobindo**

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 Aurobindo tablet (5 mg of risedronate sodium) once a day.

### **When to take the Risedronate Aurobindo tablet**

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

### **How to take the Risedronate Aurobindo 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 Aurobindo than you should**

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

### **If you forget to take Risedronate Aurobindo**

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 Aurobindo**

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 Aurobindo 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/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 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 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.

### **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

HPRA Pharmacovigilance  
Earlsfort Terrace  
IRL - Dublin 2  
Tel: +353 1 6764971  
Fax: +353 1 6762517  
Website: [www.hpra.ie](http://www.hpra.ie)  
e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie)

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

## **5. How to store Risedronate Aurobindo**

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 to protect the environment.

## **6. Contents of the pack and other information What Risedronate Aurobindo contains**

The active substance is risedronate sodium. Each film-coated tablet contains 5 mg risedronate sodium (equivalent to 4.6 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 and silica colloidal Anhydrous.

### **What Risedronate Aurobindo looks like and contents of the pack**

Film-coated tablet.

Yellow coloured, circular shaped, beveled edge, film-coated biconvex tablets debossed with 'X' on one side and '61' on the other side.

Transparent PVC / PE / PVdC / Aluminium blisters in a cardboard box, Packs 14, 20, 28, 84, 98 or 140 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

or

Milpharm Limited,  
Ares Block, Odyssey Business Park,  
West End Road, Ruslp HA46QD.  
United Kingdom

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

Ireland	Risedronate Aurobindo 5 mg film-coated tablets
Italy	Risedronato Aurobindo 5 mg
Malta	Risedronate Aurobindo 5 mg film-coated tablets
The Netherlands	Risedronaatnatrium Aurobindo 5 mg, filmomhulde tabletten
United Kingdom.	Risedronate sodium 5 mg film-coated tablets

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