IE

Package leaflet: Information for the user

Risedronate Once a Week

35mg

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 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, or talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

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

1. What Risedronate Once a Week is and what it is used for

What Risedronate Once a Week is
Risedronate Once a Week 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 Once a Week 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. What you need to know before you take Risedronate Once a Week

Do not take Risedronate Once a Week 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 before you take Risedronate Once a Week 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 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 Once a Week

Your doctor will advise you on what to do when taking Risedronate Once a Week tablets 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 Once a Week

Medicines containing one of the following lessen the effect of Risedronate Once a Week 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 Once a Week tablet.

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

Taking Risedronate Once a Week with food and drink

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

Pregnancy and breast-feeding

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

Breast-feeding
Do NOT take Risedronate if you are breast-feeding (see section 2, "Do not take Risedronate Once a Week").

Risedronate Once a Week should only be used to treat postmenopausal women and men.

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

Driving and using machines

Risedronate Once a Week is not known to affect your ability to drive and use machines.

Risedronate Once a Week tablets contains polydextrose (which contains glucose and sorbitol)
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 Once a Week

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Dosage
The recommended dose is ONE Risedronate Once a Week tablet (35 mg of risedronate sodium) once a week.

Choose one day of the week that best fits your schedule. Every week, take the Risedronate Once a Week tablet on your chosen day.

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

How to take the Risedronate Once a Week tablet
- Take the tablet whilst you are in an upright position (you may sit or stand) to avoid heartburn.
- Swallow the tablet with at least one glass (120 ml) of plain water.
  Swallow the tablet 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.

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Mylan	PEPA+			Date: 15 JUN 2016		Time: 15:30	
Description	Risedronate Sodium 35 mg 4			No. of colours	1	Page Count	1/2
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MA No.	N/A	Glams Proof No.	N/A				
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Sign-offs							
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If you take more Risedronate Once a Week than you should

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

Following substantial overdose may decrease blood serum calcium level. Signs and symptoms of hypocalcaemia such as, 'pins and needles' sensation, fatigue, anxiety and muscle cramps may also occur in some of these patients.

If you forget to take Risedronate Once a Week

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 Once a Week

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 Once a Week 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, "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 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 (may affect up to 1 in 100 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, "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 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.
- An allergic inflammation of blood vessels (leukocytoclastic vasculitis)

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.

Very rare side effects (may affect up to 1 in 10,000 patients):
- 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.

Not known side effects (frequency cannot be estimated from the available data);
- Hair loss.
- Liver disorders, some cases were severe.

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 Once a Week

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 label after EXP. The expiry date refers to the last day of that month.

This medicinal product 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 Once a Week contains

The active substance is risedronate sodium. Each film-coated tablet contains 35 mg risedronate sodium, equivalent to 32.5 mg risedronic acid.

The other ingredients are:
Tablet core: mannitol, cellulose, microcrystalline, crospovidone, silica colloidal anhydrous, and magnesium stearate.

Film-coating: Titanium dioxide (E171), polydextrose (contains glucose and sorbitol), hypromellose, macrogol 8000, triacetin, iron oxide yellow (E172) and iron oxide red (E172).

What Risedronate Once a Week looks like and contents of the pack

Film-coated tablet

Light orange film-coated tablet, round, biconvex, bevelled edge tablet debossed with **M** on one side of the tablet and **714** on the other side.

Risedronate Once a Week film-coated tablets are available in blister packs of 1, 2, 4, 10, 12, 16, 24, 28 tablets, in calendar packs of 4 tablets and in bottle packs of 1, 2, 4, 10, 12, 16, 24, 28 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

McDermott Laboratories Limited
(t/a Gerard Laboratories)
35/36 Baldoyle Industrial Estate,
Grange Road,
Dublin 13
Ireland

Manufacturer

Mylan Hungary Kft
Mylan utca 1.,
Komárom
2900
Hungary

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

Belgium	Risedronate Mylan 35 mg Wekelijks filmomhulde tabletten
Bulgaria	Risedrogen 35 mg Tablets
Czech Republic	Rismyl 35 mg, potahované tablety
Denmark	Risedronat Mylan
Finland	Risedronat Mylan 35 mg kalvopäällysteiset tabletit
France	Risedronate Mylan Pharma 35 mg, comprimé pelliculé
Germany	Risedronat-dura 35 mg Filmtabletten
Iceland	Risedronat Mylan 35 mg filmuhúðuð tafla
Ireland	Risedronate Once a Week 35mg Film-coated Tablets
Luxemburg	Risedronate Mylan 35 mg Hebdomadaire comprimés pelliculés
Norway	Risedronat Mylan 35 mg filmdrasjerte tabletter
Portugal	Risedronato de sódio Mylan
Slovakia	Rismyl 35 mg filmom obalené tablety
Spain	Risedronato Semanal Mylan 35 mg comprimidos EFG
Sweden	Risedronat Mylan 35 mg filmdragerade tabletter
The Netherlands	Risedronaatnatrium Mylan wekelijks 35 mg, filmomhulde tabletten
United Kingdom	Risedronate 35 mg film-coated tablets.

This leaflet was last revised in 11/2015.

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Mylan **PEPA+**

Description	Risedronate Sodium 35 mg 4			Date: 15 JUN 2016		Time: 15:30	
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TrackWise PR No.	911204	Trackwise Proof No.	1	Equivalent Pantone+ Color Bridge Coated colours			
MA No.	N/A	Glams Proof No.	N/A				
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Supplier Code	50061499	Keyline/Drawing No.	N/A	Dimensions	170 x 480 mm	Min Text Size used	9 pt
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Sign-offs							
							v1/May 2015