

Package leaflet: Information for the user

Risedronate Mylan Once a Week 35 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.

What is in this leaflet:

1. What Risedronate Mylan Once a Week is and what it is used for
2. What you need to know before you take Risedronate Mylan Once a Week
3. How to take Risedronate Mylan Once a Week
4. Possible side effects
5. How to store Risedronate Mylan Once a Week
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1. What Risedronate Mylan Once a Week is and what it is used for

What Risedronate Mylan Once a Week is

Risedronate Mylan 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 Mylan 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 Mylan Once a Week

Do not take Risedronate Mylan Once a Week

- 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 **hypocalcemia** (a low blood calcium level).
- if you may be **pregnant, are pregnant** or are planning to become pregnant.

- if you are **breast-feeding**.
- if you have **severe kidney problems**.
- if you are less than 18 years of age.

Warning and precautions

Talk to your doctor or pharmacist before taking Risedronate Mylan Once a Week

- 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 Mylan Once a Week.

Your doctor will advise you on what to do when taking Risedronate Mylan Once a Week if you have any of the above.

Children and adolescents

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

Other medicines and Risedronate Mylan Once a Week

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 Mylan 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 taking Risedronate Mylan Once a Week.

Risedronate Mylan Once a Week with food and drink

It is very important that you do NOT take your Risedronate Mylan 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, "Taking other medicines").

Take food and drinks (other than plain water) at least 30 minutes after your Risedronate Mylan Once a Week tablet.

Pregnancy and breast-feeding

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

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

Driving and using machines

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

Risedronate Mylan Once a Week contains lactose

Risedronate Mylan Once a Week contains a small amount of 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 (see section 2, “Take special care and talk to your doctor before you start taking Risedronate Mylan Once a Week”).

3. How to take Risedronate Mylan Once a Week

Dosage

Always take Risedronate Mylan Once a Week exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is ONE Risedronate Mylan Once a Week (35 mg risedronate sodium) once a week. Choose one day of the week that best fits your schedule. Every week, take the Risedronate Mylan Once a Week tablet on your chosen day.

There are boxes/spaces on the carton. Please mark the day of the week you have chosen to take your Risedronate Mylan Once a Week tablet. Also write in the dates you will take the tablet.

When to take your Risedronate Mylan Once a Week tablet:

Take your Risedronate Mylan 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 your Risedronate Mylan Once a Week 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 the tablet.
- Do **not lie down for 30 minutes after** taking the 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 Mylan Once a Week than you should

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

If you forget to take Risedronate Mylan Once a Week

If you have forgotten to take your tablet on 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 a double dose to make up for a forgotten tablet.

If you stop taking Risedronate Mylan 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, Risedronate Mylan Once a Week can cause side effects, although not everybody gets them.

Stop taking Risedronate Mylan 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 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, "Take special care and talk to your doctor before you start taking Risedronate Mylan Once a Week").

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 side effects (affects 1 to 10 users in 100):

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 (affects 1 to 10 users in 1,000):

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 Mylan Once a Week"), 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 (affects 1 to 10 users in 10,000):

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 side effects (affects up to 1 in 10,000 users):

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);

Allergic reactions of the skin such as urticaria (hives), skin rash, swelling of the face, lips, tongue and/or neck, difficulty in swallowing or breathing. Severe skin reactions including vesiculation (blistering) under the skin; inflammation of small blood vessels, characterised by palpable red spots on the skin (leukocytoclastic vasculitis); a serious illness called Stevens Johnson syndrome (SJS) with blistering of the skin, mouth, eyes and other moist body surfaces (genitals); a severe illness called toxic epidermal necrolysis (TEN) which causes a red rash over many parts of the body and/or loss of the outer layer of skin.

Hair loss. Allergic reactions (hypersensitivity). Serious liver disorders, mainly if you are treated with other medicinal products known to cause liver problems. Inflammation of the eye which causes pain and redness.

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, 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; 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 Mylan Once a Week

Keep out of the reach and sight of children.

This medicinal product does not require any special storage conditions.

Do not use Risedronate Mylan Once a Week after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not throw away 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 Mylan Once a Week contains

- The active substance is Risedronate sodium. Each tablet contains 35 mg risedronate sodium, equivalent to 32.5 mg risedronic acid.
- The other ingredients are:
Tablet core: Starch, pregelatinised (maize); Cellulose, microcrystalline; Crospovidone; Magnesium stearate.
Film coating: Hypromellose, Lactose monohydrate, Titanium dioxide (E171), Macrogl 4000.

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

Risedronate Mylan Once a Week are white round biconvex film-coated tablets with diameter of 11.2 mm, 5.0 mm in thickness and embossed with "35" on one side. It is supplied in blister packs containing 4, 12 tablets and calendar blister of 4 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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

Manufacturer

Pharmathen S.A., 6 Dervenakion str., 153 51 Pallini Attikis, Greece

McDermott Laboratories Ltd. T/A Gerard Laboratories,
35/36 Baldoyle Industrial Estate
Grange Road, Dublin 13, Ireland

Pharmathen International S.A., Sapes Industrial Park, Block 5, 69300 Rodopi, Greece

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

AT	Risedronat Arcana 35 mg -einmal wöchentlich – Filmtabletten
BE	Risemylan 35 mg filmomhulde tabletten
DK	Vionate
ES	Risedronato semanal Mylan Pharmaceuticals 35 mg comprimidos recubiertos con película
EL	Risedronate/ Mylan 35mg Επικαλυμμένο με λεπτό υμένιο δισκίο
IE	Risedronate Mylan Once a Week 35mg film-coated tablets
IT	Risedronato Mylan 35mg comprese rivestite con film
PT	Vicendrolin
UK	Risedronate Sodium 35mg film coated tablets

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