

Package leaflet: Information for the user

Risedronate/Calcium Mylan 35 mg / 500 mg Film-coated Tablets (Risedronate sodium and calcium)

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 or nurse.
- 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 or nurse. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

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

1. What Risedronate/Calcium Mylan is and what it is used for

A combination medicine packed as weekly units each containing 1 tablet of Risedronate Sodium (light orange tablet) and 6 tablets of Calcium (light lavender tablets).

Risedronate Sodium tablets

Risedronate Sodium tablets contain risedronate sodium which belongs to a group of non-hormonal medicines called bisphosphonates. These medicines 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. 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.

Calcium tablets

The tablets contain calcium carbonate which provide the calcium that your body may need to harden new bone.

What Risedronate/Calcium Mylan is used for

The treatment of osteoporosis in **postmenopausal women** who also need daily **calcium supplementation** as assessed by their doctor.

2. What you need to know before you take Risedronate/Calcium Mylan

Do not take Risedronate/Calcium Mylan

- If you are allergic to risedronate sodium or calcium 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)
 - **hypercalcaemia** (a high blood calcium level)
 - **hypercalciuria** (a high calcium level in the urine)

- If you may be **pregnant**, are pregnant or planning to become pregnant
- If you are **breast-feeding**
- If you have severe **kidney problems**, including kidney stones

Warnings and precautions

Talk to your doctor or, pharmacist or nurse before taking Risedronate/Calcium Mylan:

- 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/Calcium Mylan
- If you have mild to moderate kidney problems, your doctor may want to monitor levels of calcium and phosphate in your blood and urine.

Your doctor will advise you on what to do when taking Risedronate/Calcium Mylan 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/Calcium Mylan

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

Risedronate Sodium tablets (light orange tablets)

Medicines containing one of the following lessen the effect of the Risedronate Sodium tablet 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 Sodium tablet.

Calcium tablets (light lavender tablets)

Medicines containing calcium are known to interfere with the following:

- digitalis (used to treat heart disorders)
- tetracycline antibiotics
- steroids (such as cortisone)
- sodium fluoride (used to strengthen the tooth enamel)
- thiazide diuretics (used to remove water from the body by increasing urine production)

If you are taking any of the above-mentioned medicines, your doctor will give you further instructions.

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

Risedronate/Calcium Mylan with food and drink

Risedronate Sodium tablets (light orange tablets)

It is very important that you do NOT take your Risedronate Sodium tablet with food or drinks (other than plain water) so that it can work properly. In particular do not take the tablet at the same time as dairy

products (such as milk) as they contain calcium (see section 2, “Other medicines and Risedronate/Calcium Mylan”). Take food and drinks (other than plain water) at least 30 minutes after your Risedronate Sodium tablet.

Calcium tablets (light lavender tablets)

Do NOT take the Calcium tablets at the same time as foods containing high amounts of oxalic acid (spinach and rhubarb) or phytic acid (whole cereals). Take the tablets at least 2 hours after eating such foods.

Pregnancy and breast-feeding

Pregnancy

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

Breast-feeding

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

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/Calcium Mylan is not known to affect your ability to drive and use machines.

Risedronate/Calcium Mylan contains the colourant Allura red (E129)

Risedronate Sodium tablets contain the colourant Allura red (E129), which may cause allergic reactions.

Risedronate/Calcium Mylan contains glucose and sorbitol

Risedronate Sodium tablets contain 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/Calcium Mylan

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

Risedronate/Calcium Mylan is a weekly therapy presented in blister packs containing 1 Risedronate Sodium 35 mg tablet and 6 Calcium 500 mg tablets. Every weekly blister pack has dosing instructions on the back.

The recommended dose is:

Usual dose:

Weekly cycle:

- *Day 1: Risedronate Sodium tablet (light orange tablet)*

Take ONE Risedronate Sodium tablet once a week.

Choose one day of the week that best fits your schedule. This will be your Day 1 of the weekly cycle. Every week, take the Risedronate Sodium tablet on your chosen Day 1.

- *Days 2 to 7: Calcium tablets (light lavender tablets)*

Beginning on the day after the Risedronate Sodium tablet has been taken, take ONE tablet of Calcium each day for the next 6 days.

Every 7 days start a new weekly blister pack. You should begin a new blister pack by taking the Risedronate Sodium tablet on your chosen Day 1.

WHEN to take the Risedronate Sodium tablet

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

HOW to take Risedronate/Calcium Mylan tablet

Risedronate Sodium tablets (light-orange 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.

Calcium tablets (light lavender tablets)

- Take one calcium tablet each day for the next 6 days.
- **Swallow it whole**.
- It is recommended to take the calcium tablet **with a meal**.

If you take MORE Risedronate/Calcium Mylan than you should

Risedronate Sodium tablets (light orange tablets):

If you have taken more Risedronate Sodium tablets than you should, or if children have been taking the medicine by accident, drink one **full glass of milk** and **seek medical attention**.

Calcium tablets (light lavender tablets):

If you have taken more tablets than you should, or if children have been taking the medicine by accident, please contact your doctor.

If you forget to take Risedronate/Calcium Mylan

Risedronate Sodium tablets (light orange tablets)

If you have forgotten to take your tablet on your chosen day (Day 1):

1. Take it on the day you remember. Do **NOT** take two tablets in one day to make up for the tablet you missed.
2. On the following day take your Calcium tablet (*light lavender* tablet). Do **NOT** take your light orange tablet and the *light lavender* tablet on the same day.
3. Continue taking one *light lavender* tablet each day until the end of the weekly cycle.
4. Discard any remaining tablets in the blister pack at the end of the weekly cycle.
5. Then start a new weekly cycle: take one Risedronate Sodium tablet once a week on your chosen Day 1.

Calcium tablets (light lavender tablets):

If you have forgotten to take a Calcium tablet:

1. Take it on the day you remember. Do **NOT** take the *light lavender* tablet on the same day as the light orange tablet. Do **NOT** take two *light lavender* tablets on the same day.
2. Continue taking one *light lavender* tablet each day until the end of the weekly cycle.
3. Discard any remaining tablets in the blister pack at the end of the weekly cycle.

If you stop taking Risedronate/Calcium Mylan

If you stop treatment you may begin to lose bone mass. Please talk to your doctor before you consider stopping treatment.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Risedronate Sodium tablets (light orange tablets):

Stop taking Risedronate Sodium 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 Sodium”).
- 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, “Warning 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.
- 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.

Not known (frequency cannot be estimated from the available data)

During post-marketing experience, the following have been reported

- Hair loss
- Liver disorders, some cases were severe

Calcium tablets (light lavender tablets):

Uncommon side effects (may affect up to 1 in 100 patients)

- Hypercalcaemia (a high blood calcium level, with potential symptoms of excessive thirst, loss of appetite, fatigue and in severe cases irregular heart beat), hypercalciuria (a high calcium level in the urine)

Rare side effects (may affect up to 1 in 1,000 patients)

- Wind, constipation, feeling sick, abdominal pain, diarrhoea

- Rash, red raised itchy skin

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/Calcium Mylan

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 blisters 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/Calcium Mylan contains

Risedronate Sodium tablets (light orange tablets):

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: mannitol, cellulose microcrystalline, crospovidone, silica colloidal anhydrous, macrogol 8000 and magnesium stearate.

Film coating: titanium dioxide (E171), polydextrose (E1200) (contains glucose and sorbitol), hypromellose (E464), triacetin, iron oxide yellow (E172) and iron oxide red (E172)

Calcium tablets (light lavender tablets):

The active substance is calcium. Each tablet contains 1250 mg calcium carbonate, equivalent to 500 mg elemental calcium.

The other ingredients are:

Tablet core: hydroxypropyl cellulose, polysorbate 80, cellulose microcrystalline, croscarmellose sodium, talc, magnesium stearate, Indigo carmine (E132), Allura red (E129), starch pregelatinised (maize)

Film coating: hypromellose 5cP, hypromellose 15cP, macrogol 400

What Risedronate/Calcium Mylan looks like and contents of the pack

Risedronate/Calcium Mylan consists of weekly units containing:

- 1 Risedronate Sodium 35 mg film-coated tablet which is a light orange film-coated, round, biconvex, bevelled edge tablet debossed with **M** on one side of the tablet and **714** on the other side.
- 6 Calcium 500 mg film-coated tablets which is a light lavender, clear film-coated, modified oval, biconvex, bevelled edge tablet debossed with **M CC5** on one side of the tablet and blank on the other side.

The above weekly therapy is supplied in blister packs of 7, 14, 28, 84, 112 & 168 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

McDermott Laboratories Ltd. T/A Gerard Laboratories

35/36 Baldoyle Industrial Estate,
Grange Road,
Dublin 13,
Ireland

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

Belgium – Risedronate + Calcium Mylan 35 mg + 500 mg filmomhulde tabletten / comprimés
pelliculés / Filmtabletten, combinatieverpakking / boîte combinée / Kombinationspackung
Ireland – Risedronate/Calcium Mylan 35 mg/500 mg Film-coated Tablets
Netherlands – Risedronaatnatrium Mylan 35 mg en Calcium Mylan 500 mg,
combinatieverpakking, filmomhulde tabletten
Slovakia – Rismyl Combi
UK – Risedronate Sodium and Calcium 35 mg + 500 mg Film-coated Tablets

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