

Risedronate Way

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Risedronate Way?

Risedronate Way contains the active ingredient risedronate sodium. Risedronate Way is used to treat bone disease and belongs to a group of medicines called bisphosphonates. For more information, see Section [1. Why am I using Risedronate Way?](#) in the full CMI.

2. What should I know before I use Risedronate Way?

Do not use if you have ever had an allergic reaction to Risedronate Way or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section [2. What should I know before I use Risedronate Way?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Risedronate Way and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Risedronate Way ?

For osteoporosis, the usual dose is one 150 mg tablet once a month. More instructions can be found in Section [4. How do I use Risedronate Way?](#) in the full CMI.

5. What should I know while using Risedronate Way?

Things you should do	• Tell any doctors, dentists and pharmacists who are treating you that you are taking Risedronate Way. • If you require a dental procedure tell your dentist that you are taking Risedronate Way. Invasive dental procedures should be avoided where possible. • If you become pregnant while taking Risedronate Way tell your doctor or pharmacist. • If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking Risedronate Way.
Things you should not do	• Do not stop using this medicine without checking with your doctor or pharmacist. • Do not lie down for 30 minutes after taking Risedronate Way. • Do not have any food or drink, except for plain water for 30 minutes after taking this medicine. • Do not give this medicine to anyone else, even if they have the same condition as you. • Do not take this medicine to treat any other complaints unless your doctor/pharmacist tells you to.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how Risedronate Way affects you.
Drinking alcohol	• Tell your doctor if you drink alcohol.
Looking after your medicine	• Store below 25°C • Keep your tablets in the pack until it is time to take them.

For more information, see Section [5. What should I know while using Risedronate Way?](#) in the full CMI.

6. Are there any side effects?

Stop taking Risedronate Way and tell your doctor immediately if chest pain, swelling of the face, lips, mouth, throat or tongue or severe skin reactions occur. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Risedronate Way

Active ingredient: *Risedronate Sodium*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Risedronate Way. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Risedronate Way.**

Where to find information in this leaflet:

1. [Why am I using Risedronate Way?](#)
2. [What should I know before I use Risedronate Way?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use Risedronate Way ?](#)
5. [What should I know while using Risedronate Way ?](#)
6. [Are there any side effects?](#)

1. Why am I using Risedronate Way?

Risedronate Way contains the active ingredient risedronate sodium. Risedronate Way belongs to a group of medicines called bisphosphonates.

Risedronate Way is used to treat bone disease. Risedronate Way works directly on your bones to make them stronger and therefore less likely to break or fracture.

Risedronate Way 150 mg Once-a-Month tablets are used to treat:

- osteoporosis (brittle or fragile bones that may fracture easily)
- osteoporosis caused by taking steroids

These conditions are caused by changes in the way bone is normally maintained.

Understanding bone

Bone is a living tissue consisting of calcium and other minerals.

Throughout life, old bone is constantly broken down and replaced with new bone. After the age of 35, bone loss may occur faster than your body can replace it. If you lose too much bone then they become weaker and are more likely to break

Osteoporosis

Osteoporosis (brittle bone disease) is a disease that causes bones to become weaker. Weak bones break (fracture) easily.

Many patients with osteoporosis have no symptoms and may not even know that they have osteoporosis.

However osteoporosis makes you more likely to break bones when you have a fall or bump. The spine, hip and wrist are the most likely bones to break, although this can

happen to any bone in your body. Osteoporosis can also cause back pain, height loss and a curved back.

Osteoporosis is common in women after the menopause (change of life) and is also more likely to occur in women who have reached menopause early. Osteoporosis can also occur in women who have not yet reached menopause, and in men.

Long term steroid treatment can also lead to osteoporosis in both men and women.

Risedronate Way works by slowing down the process of old bone being removed.

This allows the bone-forming cells time to rebuild normal bone.

Risedronate Way also helps to rebuild bone mass. This creates stronger bone which is less likely to fracture.

Therefore Risedronate Way can help reverse the progression of osteoporosis.

Do not give Risedronate Way to children or adolescents under 18 years of age.

There have been no studies of its effects in this age group. There is no evidence that Risedronate Way is addictive.

This medicine is available only with a doctor's prescription.

2. What should I know before I use Risedronate Way?

Warnings

Do not use Risedronate Way if:

- you are allergic to risedronate sodium, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- are unable to stand or sit upright for at least 30 minutes
- have a condition called hypocalcaemia (a low level of calcium in the blood)
- have severe kidney problems.

Check with your doctor if you:

- have any other medical conditions:
 - o disturbances of bone and mineral metabolism (for example vitamin D deficiency, parathyroid hormone abnormalities)
 - o problems with the tube that takes food from your mouth to your stomach (oesophagus) such as ulcers
 - o pain, swelling or numbness of the jaw or a "heavy jaw feeling" or loosening of a tooth
- Check with your doctor or dentist to see if a dental check-up is required before starting Risedronate Way.

This is especially important if you are receiving medicines or therapy used to treat cancer or taking corticosteroids.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known whether Risedronate Way passes into breast milk.

Risedronate Way is not recommended for use during pregnancy, unless you and your doctor have discussed the risks and benefits involved.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Risedronate Way and affect how it works. These include:

- Antacids, medicines used to treat indigestion e.g. Gaviscon, Mylanta
- Other products containing calcium
- Iron supplements

You may need to stop taking these products or take them at a different time of day to Risedronate Way.

You can take aspirin while you are being treated with Risedronate Way.

Your doctor and pharmacist may have more information on medicines to be careful with while taking Risedronate Way.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Risedronate Way.

4. How do I use Risedronate Way ?

How much to take / use

- For osteoporosis, the usual dose is one 150 mg tablet once a month.
- Follow the instructions provided and use Risedronate Way until your doctor tells you to stop.

When to take / use Risedronate Way

- Take your Risedronate Way tablet in the morning, at least 30 minutes before your first meal, drink or medication of the day.

Risedronate Way is most effective when your stomach is empty.

- Take your Risedronate Way tablet while sitting or standing upright. Do not lie down immediately after swallowing it.

It is important to stay upright, for example, sitting, standing or walking around, for at least 30 minutes after swallowing your tablet. It is also very important to stay upright until after you have eaten your first food of the day. This will help make sure the tablet reaches your stomach quickly and helps avoid irritation to your oesophagus.

- Swallow your Risedronate Way tablet whole with a glass of plain water. Do not chew or suck the tablet.

It is important to take Risedronate Way with plain water only (120 mL), not mineral water. Mineral water and other drinks, including fruit juices, coffee and tea, will reduce the effect of Risedronate Way.

- **Take your Risedronate Way 150 mg tablet on the same day each month.** This tablet should be taken each month. Choose a day of the month that suits you the best.

If you forget to use Risedronate Way

Risedronate Way should be used regularly at the same time each month.

If you have forgotten to take your 150 mg tablet, and your next monthly dose is more than 7 days ahead just take one tablet the next morning.

If you have forgotten to take your 150 mg tablet, and your next monthly dose is within 7 days do not take it. Return to taking one tablet once a month, as originally scheduled on your chosen day.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you use too much Risedronate Way

If you think that you have used too much Risedronate Way, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

If you or somebody else has accidentally taken a large number of tablets, drink a full glass of milk or antacids.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Risedronate Way ?

Things you should do

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking Risedronate Way.

If you require a dental procedure, tell your dentist that you are taking Risedronate Way. Invasive dental procedures should be avoided where possible.

This type of medicine may cause jaw-bone problems in some people. Jaw-bone problems may include infection, and delayed healing after teeth are pulled out or other work that involves drilling into the jaw.

Call your doctor straight away if you:

- develop a toothache, jaw pain, painful exposed bone or swelling, especially following dental work
- are about to be started on any new medicine
- become pregnant while taking Risedronate Way
- develop new or unusual pain in your hip or thigh. Rarely, patients have experienced fracture in a specific part of the thigh bone.

Speak to your doctor and dentist about good oral hygiene and regular dental check-ups while you are using Risedronate Way.

Things you should not do

- Do not lie down for 30 minutes after taking Risedronate Way.
- Do not have any food or drink, except for plain water for 30 minutes after taking Risedronate Way
- Do not give Risedronate Way to anyone else, even if they have the same condition as you.
- Do not take Risedronate Way to treat any other complaints unless your doctor or pharmacist tells you to.
- Do not stop using this medicine suddenly without checking with your doctor or pharmacist.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Risedronate Way affects you.

Risedronate Way may cause dizziness in some people

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Keep your tablets in the pack until it is time to take them.
- If you take the tablets out of the pack they may not keep well.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; where the temperature stays below 25°C; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Do not use this medicine after the expiry date.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• stomach pain • diarrhoea • aching muscles, joints or bones • headache • nausea • runny nose • sore throat • dizziness • skin rash or redness of the skin, sometimes made worse by sunlight, itchiness • blurred vision or changes in your vision • pain swelling or redness in the eyes or your eyeball bulging out of its socket • problems with your jaw or teeth, associated with delayed healing and/or infection often following a tooth extraction or invasive dental work • difficulty or pain on swallowing* • new or worsening heartburn*	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
• chest pain* • swelling of the face, lips, mouth, throat or tongue • severe skin reactions	Stop taking Risedronate Way. Call your doctor straight away, or go straight to the

Serious side effects	What to do
	Emergency Department at your nearest hospital if you notice any of these serious side effects.

* These side effects may be due to irritation or ulceration of the food pipe. They may worsen if you continue taking the tablets.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Risedronate Way contains

Active ingredient (main ingredient)	risedronate sodium Each tablet contains 150 mg risedronate sodium
Other ingredients (inactive ingredients)	• microcrystalline cellulose • crospovidone • magnesium stearate • colloidal anhydrous silica • Opadry Blue 04F505003
Potential allergens	None

Do not take this medicine if you are allergic to any of these ingredients.

Risedronate Way does not contain sucrose, gluten, tartrazine or any other azo dyes.

What Risedronate Way looks like

Risedronate Way is a blue colored slightly biconvex oval shaped film coated tablet, RSN debossed on one side and 150 mg debossed on other side. It is supplied in a pack size of 1 tablet (AUST R 473925).

Who distributes Risedronate Way

Risedronate Way is supplied in Australia by:

Clinect Pty Ltd

120-132 Atlantic Drive,

Keysborough VIC 3173

Australia

Free Call Australia: 1800 899 005

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