

RISEDRONATE-WGR

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 taking RISEDRONATE-WGR?

RISEDRONATE-WGR contains the active ingredient risedronate sodium (as hemipentahydrate). RISEDRONATE-WGR is used to treat bone disease and belongs to a group of medicines called bisphosphonates.

For more information, see Section [1. Why am I taking RISEDRONATE-WGR?](#) in the full CMI.

2. What should I know before I take RISEDRONATE-WGR?

Do not use if you have ever had an allergic reaction to RISEDRONATE-WGR 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 take RISEDRONATE-WGR?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with RISEDRONATE-WGR 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 take RISEDRONATE-WGR?

One 35 mg tablet weekly on the same day each week or one 75 mg tablet taken on two consecutive days (two tablets in total) each month or one 150 mg tablet monthly on the same date each month.

More instructions can be found in Section [4. How do I take RISEDRONATE-WGR?](#) in the full CMI.

5. What should I know while taking RISEDRONATE-WGR?

| | |
|------------------------------------|---|
| Things you should do | <ul style="list-style-type: none">• Tell any doctors, dentists and pharmacists who are treating you that you are taking RISEDRONATE-WGR.• If you require a dental procedure tell your dentist that you are taking RISEDRONATE-WGR. Invasive dental procedures should be avoided where possible.• If you become pregnant while taking RISEDRONATE-WGR 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-WGR. |
| Things you should not do | <ul style="list-style-type: none">• Do not stop taking RISEDRONATE-WGR without checking with your doctor or pharmacist.• Do not lie down for 30 minutes after taking RISEDRONATE-WGR.• Do not have any food or drink, except for plain water for 30 minutes after taking RISEDRONATE-WGR.• Do not give RISEDRONATE-WGR to anyone else, even if they have the same condition as you.• Do not take RISEDRONATE-WGR to treat any other complaints unless your doctor or pharmacist tells you to. |
| Driving or using machines | <ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how RISEDRONATE-WGR affects you. |
| Drinking alcohol | <ul style="list-style-type: none">• Tell your doctor if you drink alcohol. |
| Looking after your medicine | <ul style="list-style-type: none">• 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 taking RISEDRONATE-WGR?](#) in the full CMI.

6. Are there any side effects?

Stop taking RISEDRONATE-WGR 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-WGR

Active ingredient: *risedronate sodium (as hemipentahydrate)*

Consumer Medicine Information (CMI)

This leaflet provides important information about taking RISEDRONATE-WGR. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking RISEDRONATE-WGR.**

Where to find information in this leaflet:

- [1. Why am I taking RISEDRONATE-WGR?](#)
- [2. What should I know before I take RISEDRONATE-WGR?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take RISEDRONATE-WGR?](#)
- [5. What should I know while taking RISEDRONATE-WGR?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I taking RISEDRONATE-WGR?

RISEDRONATE-WGR contains the active ingredient risedronate sodium (as hemipentahydrate).

RISEDRONATE-WGR belongs to a group of medicines called bisphosphonates.

RISEDRONATE-WGR is used to treat bone disease:

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

RISEDRONATE-WGR works directly on your bones to make them stronger and therefore less likely to break or fracture.

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 the 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-WGR works by slowing down the process of old bone being removed.

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

RISEDRONATE-WGR also helps to rebuild bone mass. This creates stronger bone which is less likely to fracture.

Therefore RISEDRONATE-WGR can help reverse the progression of osteoporosis.

Do not give RISEDRONATE-WGR 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-WGR is addictive.

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

2. What should I know before I take RISEDRONATE-WGR?

Warnings

Do not take RISEDRONATE-WGR if:

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

Check with your doctor if you:

- have any other medical conditions:
 - Disturbances of bone mineral metabolism (for example vitamin D deficiency, parathyroid hormone abnormalities).
 - Problems with the tube that takes food from your mouth to your stomach (oesophagus) such as ulcers.
 - 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-WGR. 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-WGR passes into breast milk.

RISEDRONATE-WGR 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-WGR 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-WGR.

You can take aspirin while you are being treated with RISEDRONATE-WGR.

Your doctor and pharmacist may have more information on medicines to be careful with while taking RISEDRONATE-WGR.

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-WGR.

4. How do I take RISEDRONATE-WGR?

How much to take

- One 35 mg tablet weekly on the same day each week; or
- One 75 mg tablet taken on two consecutive days (two tablets in total) each month; or
- One 150 mg tablet monthly on the same date each month. Choose a day of the month that suits you the best.
- Taking your tablets at the same time each day will have the best effect. It will also help you remember when to take the tablets.
- Follow the instructions provided and take RISEDRONATE-WGR until your doctor tells you to stop.

When to take RISEDRONATE-WGR

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

RISEDRONATE-WGR is most effective when your stomach is empty.

- Take your RISEDRONATE-WGR 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-WGR tablet whole with a glass of plain water. Do not chew or suck the tablet.

It is important to take RISEDRONATE-WGR 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-WGR.

If you forget to take RISEDRONATE-WGR

RISEDRONATE-WGR should be taken regularly at the same time each day or month.

RISEDRONATE-WGR 35 mg Tablet

If you have forgotten to take your 35 mg tablet, take your tablet on the day you remember. Do not take two tablets on the same day to make up for the missed dose. Return to taking one tablet once a week on your original chosen day.

RISEDRONATE-WGR 75 mg Tablet

If you have forgotten to take one or both of your 75 mg tablets and it is more than 7 days until your next monthly doses are due, take the missed doses in the morning after the day you remembered (and the next morning if you missed both doses).

If the missed dose is within 7 days of your next month's doses, wait until the doses are next due and then continue taking your tablets as normal.

RISEDRONATE-WGR 150 mg Tablet

If you have forgotten to take your 150 mg tablet and it is more than 7 days until your next monthly dose is due, take the missed dose in the morning after the day you remembered.

If the missed dose is within 7 days of your next month's dose, do not take your missed dose. Wait until the date you would normally take your tablet and continue taking your tablets as normal.

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 take too much RISEDRONATE-WGR

If you think that you have taken too much RISEDRONATE-WGR, 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 taking RISEDRONATE-WGR

Things you should do

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking RISEDRONATE-WGR.

If you require a dental procedure, tell your dentist that you are taking RISEDRONATE-WGR. 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 or dentist 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-WGR.
- 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 taking RISEDRONATE-WGR.

Things you should not do

- Do not lie down for 30 minutes after taking RISEDRONATE-WGR.
- Do not have any food or drink, except plain water for 30 minutes after taking RISEDRONATE-WGR.
- Do not give RISEDRONATE-WGR to anyone else, even if they have the same condition as you.
- Do not take RISEDRONATE-WGR to treat any other complaints unless your doctor or pharmacist tells you to.
- Do not stop taking RISEDRONATE-WGR 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-WGR affects you.

RISEDRONATE-WGR 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 on 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:

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

Heat and dampness can destroy some medicines.

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 take RISEDRONATE-WGR or it is out of date, take it to any pharmacy for safe disposal.

Do not take RISEDRONATE-WGR after the expiry date.

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 |
|---|---|
| <ul style="list-style-type: none">• 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 | <p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> |

| Less serious side effects | What to do |
|---|------------|
| tooth extraction or invasive dental work. • Difficulty or pain with swallowing*. • New or worsening heartburn*. | |

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

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-WGR. Call your doctor straight away, or go straight to the 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

RISEDRONATE-WGR is only available with a doctor's prescription.

What RISEDRONATE-WGR contains

| | |
|---|---|
| Active ingredient (main ingredient) | Each tablet contains 35 mg, 75 mg or 150 mg of risedronate sodium (as hemipentahydrate) as the active ingredient. |
| Other ingredients (inactive ingredients) | <ul style="list-style-type: none"> • Lactose monohydrate. • Crospovidone. • Magnesium stearate. • Colloidal anhydrous silica. |

| | |
|----------------------------|--|
| | <ul style="list-style-type: none"> • Hypromellose. • Hyprollose. • Macrogol 8000. • Titanium dioxide • Iron oxide red (35 mg and 75 mg tablets only). • Iron oxide yellow (35 mg tablet only). • Indigo carmine aluminium lake (150 mg tablet only). • Monobasic sodium phosphate dihydrate (150 mg tablet only). • Dibasic sodium phosphate (150 mg tablet only) |
| Potential allergens | Contains sugars as lactose (150 mg tablet). |

RISEDRONATE-WGR does not contain gluten, sucrose, tartrazine or any other azo dyes.

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

What RISEDRONATE-WGR looks like

RISEDRONATE-WGR 35 mg Tablet*

Orange, round, biconvex coated tablets, engraved "APO" on one side, "RIS" over "35" on the other side.

Blister packs of 1, 4, 8, 12 and 16 tablets. AUST R 160636*.

RISEDRONATE-WGR 75 mg Tablet*

Dark pink, round, biconvex coated tablets, engraved "APO" on one side, "RIS" over "75" on the other side.

Blister packs of 2, 4, 6 and 8 tablets. AUST R 181976*.

RISEDRONATE-WGR 150 mg Tablet*

Blue, round, biconvex coated tablets, engraved "APO" on one side, "RIS" over "150" on the other side.

Blister packs of 1, 2, 3 and 4 tablets. AUST R 181972*.

* Not all strengths and pack sizes may be available.

Who distributes RISEDRONATE-WGR

Wagner Pharmaceuticals Pty Ltd

6 Albert Street

Preston VIC 3072

Tel: 1800 936 140

This leaflet was prepared in June 2025.