

Actonel®

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 Actonel?

Actonel contains the active ingredient risedronate sodium. Actonel 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 Actonel?](#) in the full CMI.

2. What should I know before I use Actonel

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

3. What if I am taking other medicines?

Some medicines may interfere with Actonel 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 Actonel?

For osteoporosis, the usual dose is one 5mg tablet each day or one 150mg tablet once a month. For Paget's disease of the bone, the usual dose is one 30 mg tablet each day for 2 months. More instructions can be found in Section [4. How do I use Actonel?](#) in the full CMI.

5. What should I know while using Actonel?

Things you should do

- Tell any doctors, dentists and pharmacists who are treating you that you are taking Actonel.
- If you require a dental procedure tell your dentist that you are taking Actonel. Invasive dental procedures should be avoided where possible.

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| | <ul style="list-style-type: none"> ● If you become pregnant while taking Actonel 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 Actonel. |
| <p>Things you should not do</p> | <ul style="list-style-type: none"> ● Do not stop using this medicine without checking with your doctor or pharmacist. ● Do not lie down for 30 minutes after taking Actonel ● Do not have any food or drink, except for plain water for 30 minutes after taking Actonel ● Do not give Actonel to anyone else, even if they have the same condition as you ● Do not take Actonel 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 Actonel 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 using Actonel?](#) in the full CMI.

6. Are there any side effects?

Stop taking Actonel 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.

Actonel

Active ingredient(s): risedronate sodium

Consumer Medicine Information (CMI)

This leaflet provides important information about using Actonel. **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 Actonel.**

Where to find information in this leaflet:

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

1. Why am I using Actonel?

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

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

Actonel 5mg daily, and 150mg Once-a-Month tablets are used to treat:

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

Actonel 30mg tablets are used to treat:

- -Paget's disease of the bone

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 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.

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

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

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

Therefore Actonel can help reverse the progression of osteoporosis.

Paget's disease of the bone

Paget's disease occurs when the process of bone remodelling happens too quickly and in a disordered way. The new bone that is produced is weaker than normal and the affected bones may become enlarged, deformed, painful and may fracture. The skull,

spine, legs, collar bone and pelvic bone are the most commonly affected.

Do not give Actonel 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 Actonel is addictive.

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

2. What should I know before I use Actonel?

Warnings

Do not use Actonel if:

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

Check with your doctor if you:

- have any other medical conditions:
 - disturbances of bone and 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 Actonel. 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 Actonel passes into breast milk.

Actonel 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 Actonel 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 Actonel.

You can take aspirin while you are being treated with Actonel.

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

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

4. How do I use Actonel?

How much to take / use

- For osteoporosis, the usual dose is one 5mg tablet each day, or one 150mg tablet once a month.
- For Paget's disease of the bone, the usual dose is one 30 mg tablet each day for 2 months
- Follow the instructions provided and use Actonel until your doctor tells you to stop.

When to take / use Actonel

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

Actonel is most effective when your stomach is empty.

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

It is important to take Actonel 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 Actonel.

Take your Actonel 5mg and 30mg tablet at the same time of day every day.

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.

Take your Actonel 150mg Once-a- Month 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 Actonel

Actonel should be used regularly at the same time each day or month.

For Actonel 5mg and 30mg Tablets:

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Do not take a double dose to make up for the tablet that you missed.

This may increase the chance of you getting an unwanted side effect.

For Actonel 150mg Once-a-Month tablets:

If you have forgotten to take your 150mg 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 150mg 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 Actonel

If you think that you have used too much Actonel, 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 Actonel?

Things you should do

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

If you require a dental procedure, tell your dentist that you are taking Actonel. 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:

- you develop a toothache, jaw pain, painful exposed bone or swelling, especially following dental work
- If you are about to be started on any new medicine
- become pregnant while taking Actonel
- If you 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 Actonel.

Things you should not do

- Do not lie down for 30 minutes after taking Actonel.
- Do not have any food or drink, except for plain water for 30 minutes after taking Actonel
- Do not give Actonel to anyone else, even if they have the same condition as you.
- Do not take Actonel 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 Actonel affects you.

Actonel 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 |
|--|---|
| <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, pain or redness in the eyes● 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* | <p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> |

Serious side effects

| Serious side effects | What to do |
|---|--|
| <ul style="list-style-type: none">• chest pain*• swelling of the face, lips, mouth, throat or tongue• severe skin reactions | Stop taking Actonel. 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

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

What Actonel contains

| | |
|---|---|
| Active ingredient (main ingredient) | risedronate sodium |
| Other ingredients (inactive ingredients) | <ul style="list-style-type: none">● microcrystalline cellulose● lactose monohydrate (5mg, and 30mg only)● crospovidone● magnesium stearate● hypromellose● macrogol 400● macrogol 8000● colloidal anhydrous silica● titanium dioxide● hyprollose● iron oxide yellow (5mg only) |

- | | |
|--|--|
| | <ul style="list-style-type: none">• indigo carmine CI73015 (150mg tablet only) |
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Each Actonel 5mg tablet contains 5 mg risedronate sodium per tablet

Each Actonel 30mg tablet contains 30mg risedronate sodium per tablet

Actonel 150mg Once-a-Month tablets: 150mg risedronate sodium per tablet

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

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

What Actonel looks like

- Actonel is available in three types of tablets:
- Actonel 5mg - oval yellow tablet, with RSN marked on one side and 5mg marked on the other
- Actonel 30mg - oval white tablet, with RSN marked on one side and 30mg marked on the other
- Actonel 150mg - oval light blue tablet, with RSN marked on one side and 150mg marked on the other.

The 5mg and 30mg tablets are supplied in pack sizes of 28 tablets.

The 150mg tablets are supplied in a pack size of 1 tablet.

Australian Registration Number:

Actonel 5 mg - AUST R 74135

Actonel 30 mg - AUST R 74136

Actonel 150 mg - AUST R 150618

Who distributes Actonel

Actonel is supplied in Australia by:

Theramex Australia Pty Ltd

Level 22, 60 Margaret Street,

Sydney NSW 2000

1800 THERAMEX or 1800 843 726

This leaflet was updated in April 2021