

Actonel(R)

risedronate sodium

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Actonel.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Actonel against the benefits this medicine is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Actonel is used for

Actonel is used to treat bone disease and belongs to a group of medicines called bisphosphonates.

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

Actonel 5mg daily and 35mg Once-a-Week 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.

Before you take Actonel

When you must not take Actonel

Do not take Actonel if:

- * you have an allergy to Actonel or any of the ingredients listed at the end of this leaflet

- * 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)

Do not take Actonel if you are pregnant.

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

Do not take Actonel if you are breastfeeding.

It is not known whether Actonel passes into breast milk.

Do not take Actonel after the expiry date printed on the pack.

If you take this medicine after the expiry date has passed, it may not work as well.

Do not take Actonel if the packaging is torn or shows signs of tampering.

Talk to your doctor or pharmacist if you are not sure whether you should start taking Actonel.

Before you start to take it

Tell your doctor or pharmacist if you have allergies to:

- * any other medicines
- * any other substances, such as foods, preservatives or dyes

Tell your doctor if you are pregnant or intend to become pregnant.

Your doctor will discuss the possible risks and benefits of using Actonel during pregnancy.

Tell your doctor or pharmacist if you are breastfeeding or plan to breastfeed.

Tell your doctor if you have or have had any medical conditions, especially the following:

- * 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

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, such as prednisone or cortisone.

Tell your doctor about any of the above, before you start taking Actonel.

Taking other medicines

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

Some medicines and Actonel may interfere with each other if taken at the same time. These include:

- * Antacids, medicines used to treat indigestion eg Gaviscon, Mylanta
- * Other products containing calcium
- * Iron supplements

Check with your doctor or pharmacist if you are not sure whether you are taking any of these products.

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.

How to take Actonel

How much to take

For osteoporosis, the usual dose is one 5mg tablet each day or one Actonel 35mg tablet once a week.

For Paget's disease of the bone, the usual dose is one 30 mg tablet each day for 2 months.

Follow all directions given to you by your doctor or pharmacist.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How to take it

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.

When to take it

Take Actonel in the morning, 30 minutes to 1 hour before your first meal, drink or medication of the day.

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 35mg Once-a-Week tablet on the same day each week.

This tablet should be taken each week. Choose a day of the week that suits you the best.

If you forget to take your tablet

For Actonel 5mg and 30mg tablets:

If it is almost time for your next tablet skip the tablet you missed and take your next tablet 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 35mg Once-a-Week tablets:

If you have forgotten to take your 35mg tablet, just take your tablet on the day you remember.

Do not take two tablets in one day to make up for the tablet you missed. Return to taking one tablet once a week, 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.

How long to take it

Continue taking Actonel for as long as your doctor recommends it.

Do not stop taking Actonel without checking with your doctor or pharmacist.

If you take too much (overdose)

Immediately telephone your doctor or pharmacist or the Poisons Information Centre (13 11 26) or go to accident and emergency 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. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using Actonel

Things you must 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.

If you develop a toothache, jaw pain, painful exposed bone or swelling, especially following dental work, tell your doctor or dentist immediately.

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

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking Actonel.

If you become pregnant while taking Actonel tell your doctor or pharmacist.

Things you must 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 taking Actonel without checking with your doctor or pharmacist.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Actonel.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- * **stomach pain**
- * **diarrhoea**
- * **aching muscles, joints or bones**
- * **headache**
- * **nausea**
- * **runny nose**
- * **sore throat**
- * **dizziness**

These side effects are usually mild.

Tell your doctor immediately if you notice any of the following:

- * **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**

These side-effects are rare.

If any of the following happen, stop taking Actonel and tell your doctor immediately:

- * **difficulty or pain on swallowing**
- * **chest pain**

* **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. These side effects are rare.

If any of the following happen, stop taking Actonel and tell your doctor immediately or go to accident and emergency at your nearest hospital:

- * **swelling of the face, lips, mouth, throat or tongue**
- * **severe skin reactions**

These may be serious side effects. You may need urgent medical attention.

Other side effects not listed above may occur in some patients.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After using Actonel

Storage

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.

Keep your tablets in a cool dry place where the temperature stays below 25 degrees C.

Do not store Actonel or any other medicine in the bathroom or near a sink.

Do not leave medicines in the car on hot days or on window sills.

Heat and dampness can destroy some medicines.

Keep medicines where children cannot reach it.

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

Disposal

If your doctor or pharmacist tells you to stop taking Actonel or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

Product description

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 35mg Once-a-Week - oval light orange tablet, with RSN marked on one side and 35mg marked on the other

Ingredients

Active ingredient:

Each Actonel 5mg tablet contains 5 mg risedronate sodium per tablet

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

Each Actonel 35mg Once-a-Week tablet contains 35 mg risedronate sodium per tablet

Other inactive ingredients include:

- * microcrystalline cellulose
- * lactose
- * crospovidone
- * magnesium stearate
- * hypromellose
- * macrogol 400
- * macrogol 8000
- * silicon dioxide
- * titanium dioxide
- * hydroxypropylcellulose
- * iron oxide yellow (5mg and 35mg tablets only)
- * iron oxide red (35mg tablet only)

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

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

The 35mg tablets are supplied in pack sizes of 1 and 4 tablets.

Australian Registration Numbers:

Actonel 5 mg - AUST R 74135

Actonel 30 mg - AUST R 74136

Actonel 35 mg - AUST R 82746

Supplier

Actonel is supplied in Australia by:
sanofi-aventis australia pty ltd
12-24 Talavera Road
Macquarie Park NSW 2113

Actonel is supplied in New Zealand by:
sanofi-aventis new zealand ltd
56 Cawley St
Ellerslie, Auckland,
New Zealand

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