

RISEDRO ONCE A WEEK

risedronate sodium

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about RISEDRO ONCE A WEEK.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking RISEDRO ONCE A WEEK against the benefits they expect it will have for you.

Talk to your doctor or pharmacist if you have any concerns about taking this medicine.

Keep this leaflet with your medicine. You may need to read it again.

What RISEDRO ONCE A WEEK is used for

RISEDRO ONCE A WEEK is used to treat bone disease and belongs to a group of medicines called bisphosphonates.

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

The tablets are used to treat:

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

Osteoporosis is caused by changes in the way bone is normally maintained.

Understanding bone

Bone is living, growing tissue consisting of calcium and other minerals. Throughout life, our bodies are breaking down old bone and rebuilding new bone in a continuous cycle. Until our late 20s, while bones are still developing, we gain bone by building more than we lose. From then until about age 35 the process is usually in balance, so that the amount of bone lost is about equal to the amount that is replaced. After about age 35 this balance is disturbed, with bone loss occurring at a slightly faster rate than it can be replaced. In women, after menopause, hormonal changes cause bone loss at an even faster rate. When bone loss is excessive, bones can become thinner and weaker, and therefore are more likely to break.

Osteoporosis

"Osteo" means bone, and "porosis" means something that has holes in it, like a sponge. Therefore, osteoporosis is a disease which causes bones to become more porous, gradually making them weaker, more brittle and likely to break.

Osteoporosis is common in postmenopausal women. The menopause occurs when the ovaries virtually stop producing the female hormone, oestrogen, or are removed (which may occur, for example, at the time of a hysterectomy). At this time, bone is removed faster than it is formed, so bone loss occurs and bones become weaker. The earlier a woman reaches the menopause, the greater the risk of osteoporosis.

Osteoporosis also occurs in men but is less common than in women.

Early on, osteoporosis usually has no symptoms. However, if left untreated it can result in broken bones, also called fractures. Although fractures usually cause pain,

fractures of the bones of the spine may go unnoticed until they cause height loss. Fractures may occur during normal, everyday activity, such as lifting, or from minor injury that would not ordinarily fracture normal bone. Fractures usually occur at the hip, spine, or wrist and can lead not only to pain, but also to considerable deformity and disability, such as stooped posture from curvature of the spine, and loss of mobility.

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

RISEDRO ONCE A WEEK works by slowing down the process of old bone being removed, which allows the bone forming cells time to rebuild normal bone. It not only helps prevent the loss of bone but actually helps to rebuild bone and makes bone less likely to fracture. Thus, it reverses the progression of osteoporosis. Although it starts working on the bone cells immediately, measurable effects on bone mass may not be seen for several months or more.

Do not give RISEDRO ONCE A WEEK to children or adolescents under 18 years of age.

There have been no studies of its effects in this age group.

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

There is no evidence that RISEDRO ONCE A WEEK is addictive.

Before you take it

When you must not take it

Do not take RISEDRO ONCE A WEEK if you are allergic to risedronate sodium or any of the ingredients listed at the end of this leaflet.

Do not take it if you:

- have certain disorders of the food pipe (also called oesophagus), including those that cause difficulty swallowing
- are unable to stand or sit upright for at least 30 minutes
- have low levels of calcium in your blood (a condition called hypocalcaemia).

Do not take it if you are pregnant.

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

Do not take it if you are breastfeeding.

It is not known whether RISEDRO ONCE A WEEK passes into breast milk.

Do not take it if the expiry date (Exp.) printed on the pack has passed.

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

Do not take RISEDRO ONCE A WEEK if the packaging shows signs of tampering or the tablets do not look quite right.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you plan to become pregnant or 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.
- 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 RISEDRO ONCE A WEEK.

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 if you are planning to have any dental procedures or dental surgery.

If you know that you need to have any dental work performed, make sure that you discuss this with your doctor as they may decide it is best to delay the commencement of RISEDRO ONCE A WEEK until the work has been completed.

If you have not told your doctor about any of the above, tell them before you start taking RISEDRO ONCE A WEEK.

Taking other medicines

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

Some medicines may affect the way other medicines work.

Some medicines are likely to interfere with the absorption of RISEDRO ONCE A WEEK if taken at the same time. These include:

- antacids, used to treat indigestion eg Gaviscon, Mylanta
- calcium supplements or products containing calcium
- iron supplements.

Therefore, take RISEDRO ONCE A WEEK at least 30 minutes before taking any of these and other medicines to make sure there is no problem with absorption.

You can take aspirin while you are being treated with RISEDRO ONCE A WEEK. However, both aspirin and RISEDRO ONCE A WEEK can increase the chance of a stomach upset.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicine to be careful with or avoid while taking RISEDRO ONCE A WEEK.

How to take it

How much to take

Take RISEDRO ONCE A WEEK only when prescribed by your doctor.

For osteoporosis, the usual dose is one 35 mg tablet each week.

Follow all directions given to you by your doctor and pharmacist carefully.

When and how to take it

Take **RISEDRO ONCE A WEEK** after getting up for the day and before taking your first food, beverage, or other medication. Do not take it at bedtime.

Swallow the tablet whole with a full glass of plain water.

It is important to take it with plain water only, not mineral water. Mineral water and other drinks, including fruit juices, coffee and tea, will reduce the effect of RISEDRO ONCE A WEEK by interfering with its absorption into the body.

Stay upright for at least 30 minutes after swallowing the tablet and do not take any food, medicines or drinks other than plain water during this time.

Do not lie down immediately after swallowing it.

It is important to stay upright (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. These actions will help make sure your tablet reaches your stomach quickly and help reduce the potential for irritation to your food pipe (oesophagus).

How long to take it

Continue taking RISEDRO ONCE A WEEK for as long as recommended by your doctor. Do not stop taking it without checking with your doctor or pharmacist.

If you forget to take it

If you forget to take RISEDRO ONCE A WEEK, take your next dose the following morning.

If you take the forgotten tablet after you have eaten or had a drink, it will not work as well as it should. Therefore, it is better to skip the dose that you missed.

Do not take two tablets on the same day to make up for the dose that you missed. Return to taking one tablet once a week, as originally scheduled on your chosen day.

Talk to your doctor or pharmacist if you are not sure what to do.

If you take too much RISEDRO ONCE A WEEK (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (13 11 26), or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much RISEDRO ONCE A WEEK. Do this even if there are no signs of discomfort or poisoning.

If you take too many tablets at one time, drink a full glass of milk or antacids. Do not induce vomiting. Do not lie down.

While you are taking RISEDRO ONCE A WEEK

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking RISEDRO ONCE A WEEK.

Tell all the doctors, dentists, oral or facial surgeons and pharmacists who are treating you that you are taking the medicine.

It 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.

Ensure that you maintain good oral hygiene while you are taking RISEDRO ONCE A WEEK, especially following any dental procedure.

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

If you become pregnant while taking RISEDRO ONCE A WEEK, stop taking the tablets and tell your doctor.

If you develop difficulty or pain upon swallowing, chest pain, or new or worsening heartburn, stop taking RISEDRO ONCE A WEEK and tell your doctor.

Make sure you have an adequate intake of calcium in your diet.

Your doctor, dietician or pharmacist can tell you what foods you should eat.

Things you must not do

Do not use RISEDRO ONCE A WEEK to treat any other conditions unless your doctor tells you to.

Do not give RISEDRO ONCE A WEEK to anyone else, even if they have the same condition as you.

Do not lie down for 30 minutes after taking a dose.

Do not have any food or drink, except for plain water for 30 minutes after taking it.

Things that would be helpful for your osteoporosis

Some self help measures suggested below may help your osteoporosis. Talk to your doctor or pharmacist about these measures and for more information.

- Exercise - can be helpful in building and maintaining strong bones. Regular exercise such as a brisk walk is a good idea. Talk to your doctor before you begin any exercise program.
- Diet - eat a balanced diet. You may need to increase the amount of calcium in your diet by eating calcium-rich foods or taking a calcium supplement with vitamin D to aid calcium absorption. Your doctor will advise you.
- Smoking - appears to increase the rate at which you lose bone and, therefore, may increase your risk of fracture. Your doctor may ask you to stop smoking or at least cut down.
- Alcohol - your doctor may advise you to cut down the amount of alcohol you drink. If you drink excessively on a regular basis, you may increase your risk of developing osteoporosis.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking RISEDRO ONCE A WEEK.

Like all other medicines, it may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

You may not experience any of them.

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

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

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

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

- skin rash or redness of the skin, sometimes made worse by sunlight, itchiness
- mouth ulcers
- blurred vision, pain or redness of the eyes
- jaw or teeth problems, associated with delayed healing and/or infection, often following a tooth extraction or invasive dental procedure

Tell your dentist as well as your doctor if jaw problems develop.

These side effects are rare.

If any of the following happen, stop taking RISEDRO ONCE A WEEK and tell your doctor immediately:

- difficulty or pain upon 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 the medicine and tell your doctor immediately, or go to Accident and Emergency at the nearest hospital:

- swelling of the face, lips, mouth, throat or tongue which may cause difficulty in breathing or swallowing
- severe skin reactions.

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

Other side effects not listed above may also occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

After using it

Storage

Keep RISEDRO ONCE A WEEK 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.

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the blister pack, they may not keep well.

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

Do not store RISEDRO ONCE A WEEK or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

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

Product description

What it looks like

RISEDRO ONCE A WEEK is a white to off-white capsule shaped tablet with RE 35 on one side.

RISEDRO ONCE A WEEK comes in a blister pack of 4 tablets.

Ingredients

The active ingredient in RISEDRO ONCE A WEEK is risedronate sodium. Each tablet contains 35 mg of risedronate sodium.

The tablets also contain:

- microcrystalline cellulose
- sorbitol
- colloidal anhydrous silica
- croscarmellose sodium
- sodium stearyl fumarate.

The tablets do not contain gluten, sucrose, tartrazine or any other azo dyes.

Supplier

Arrow Pharma Pty Ltd
15 – 17 Chapel Street
Cremorne VIC 3121

Australian registration number:

RISEDRO ONCE A WEEK – AUST R
162455

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