

## RISEDRONATE AN

*Risedronate Sodium (as hemipentahydrate)*

### Consumer Medicine Information

#### What is in this leaflet

This leaflet answers some common questions about RISEDRONATE AN.

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 RISEDRONATE AN 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 RISEDRONATE AN is used for

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

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

RISEDRONATE AN 5mg daily & 35mg Once-a-Week tablets are used to treat:

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

RISEDRONATE AN 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.

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

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

RISEDRONATE AN also helps to rebuild bone mass. This creates stronger bone which is less likely to fracture. Therefore RISEDRONATE AN 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 RISEDRONATE AN 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 AN is addictive.

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

#### Before you take RISEDRONATE AN

##### *When you must not take RISEDRONATE AN*

**Do not take RISEDRONATE AN if:**

- you have an allergy to RISEDRONATE AN 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 RISEDRONATE AN if you are pregnant.**

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

**Do not take RISEDRONATE AN if you are breastfeeding.**

It is not known whether RISEDRONATE AN passes into breast milk.

**Do not take RISEDRONATE AN 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 RISEDRONATE AN 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 RISEDRONATE AN.**

##### *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 RISEDRONATE AN 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 RISEDRONATE AN.**

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 RISEDRONATE AN.**

##### *Taking other medicines*

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

Some medicines and RISEDRONATE AN 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 RISEDRONATE AN.

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

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

#### How to take RISEDRONATE AN

##### *How much to take*

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

For Paget's disease of the bone, the usual dose is one 30mg 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 RISEDRONATE AN tablet in the morning, at least 30 minutes before your first meal, drink or medication of the day.**

RISEDRONATE AN is most effective when your stomach is empty.

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

It is important to take RISEDRONATE AN 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 AN.

#### *When to take it*

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

Take your RISEDRONATE AN 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 RISEDRONATE AN 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 RISEDRONATE AN 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 RISEDRONATE AN 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 RISEDRONATE AN for as long as your doctor recommends it.

Do not stop taking RISEDRONATE AN 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.

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While you are using RISEDRONATE AN

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#### *Things you must do*

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

If you require a dental procedure, tell your dentist that you are taking RISEDRONATE AN. 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 RISEDRONATE AN.

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

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

If you develop new or unusual pain in your hip or thigh, tell your doctor. Rarely, patients have experienced fracture in a specific part of the thigh bone.

#### *Things you must not do*

Do not lie down for 30 minutes after taking RISEDRONATE AN.

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

Do not give RISEDRONATE AN to anyone else, even if they have the same condition as you.

Do not take RISEDRONATE AN to treat any other complaints unless your doctor or pharmacist tells you to.

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

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#### Side effects

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

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 RISEDRONATE AN 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 RISEDRONATE AN 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.

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#### After using RISEDRONATE AN

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##### *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°C.

Do not store RISEDRONATE AN 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 RISEDRONATE AN or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

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#### Product description

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##### *What RISEDRONATE AN looks like*

RISEDRONATE AN 5mg, 30mg & 35mg (5mg, 30mg & 35mg) is presented in a blister pack.

RISEDRONATE AN 5mg & 30mg tablets are available in pack sizes of 14 & 28 tablets.

RISEDRONATE AN 35mg tablets are available in pack size of 4 tablets.

- RISEDRONATE AN 5mg (AUST R 190160)

Yellow colored, circular shaped, beveled edge, film-coated biconvex tablets debossed with 'X' on one side and '61' on the other side.

- **RISEDRONATE AN 30mg (AUST R 190159)**

White to off-white colored, circular shaped film coated biconvex tablets debossed with 'L' on one side and '30' on the other side.

- **RISEDRONATE AN 35mg (AUST R 190157)**

Light orange colored, circular shaped film coated biconvex tablets debossed with 'F27' on one side and plain on the other side.

### *Ingredients*

**Active ingredient:**

Risedronate Sodium Hemipentahydrate

**Inactive ingredients:**

- microcrystalline cellulose
- lactose
- crospovidone
- magnesium stearate
- hydroxypropylcellulose

Each RISEDRONATE AN 5mg tablet also contains Opadry Yellow 20C82695 (PI ARTG-106484).

Each RISEDRONATE AN 30mg tablet also contains hypromellose, macrogol 400 & titanium dioxide.

Each RISEDRONATE AN 35mg tablet also contains Opadry Brown 20C86893 (PI ARTG-106485).

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

### *Name and Address of the Sponsor*

**Amneal Pharma Australia Pty Ltd**

12 River Street, South Yarra  
VIC 3141  
Australia

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