

APO-Risedronate Tablets

Contains the active ingredient risedronate sodium (as hemipentahydrate)

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about risedronate. It does not take the place of talking to your doctor or pharmacist. You can also download the most up to date leaflet from www.apotex.com.au.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

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

What this medicine is used for

The name of your medicine is APO-Risedronate. It contains the active ingredient, risedronate sodium.

This medicine is used to:

- treat osteoporosis (brittle or fragile bones that may fracture easily)
- treat osteoporosis caused by taking steroids
- preserve bone mineral density in patients on long term steroid therapy.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed this medicine for another reason.

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

How it works

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 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 works by slowing down the process of old bone being removed. This allows the bone-forming cells time to rebuild normal bone.

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

Therefore risedronate can help reverse the progression of osteoporosis.

There is no evidence that this medicine is addictive.

Use in children

Do not give risedronate to children or adolescents under 18 years of age, the safety and efficacy of risedronate has not been established in this age group.

Before you use this medicine

When you must not use it

Do not use this medicine if:

- **Do not take this medicine if you are unable to stand or sit upright for at least 30 minutes.**
- **Do not take this medicine if you have a condition called hypocalcaemia (a low level of calcium in the blood).**
- **You have had an allergic reaction to risedronate sodium**

or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin; fainting or hayfever-like symptoms.

If you think you are having an allergic reaction, do not take any more of this medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- **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.
- **The packaging is torn, shows signs of tampering or it does not look quite right.**

If you are not sure whether you should start taking this medicine, talk to your doctor or pharmacist.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
 2. 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 risedronate.**

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.

3. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.
4. You are currently breastfeeding or you plan to breastfeed. Do not take this medicine whilst breastfeeding until you and your doctor have discussed the risks and benefits involved.
5. You are planning to have surgery or an anaesthetic.
6. You are currently receiving or are planning to receive dental treatment.
Remember, check with your doctor or dentist to see if a dental check-up is required before starting risedronate.

If you have not told your doctor about any of the above, tell them before you use this medicine.

This is especially important if you are receiving medicines or therapy used to treat cancer or taking corticosteroids, such as prednisone or cortisone.

Taking other medicines

Tell your doctor 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 risedronate may interfere with each other. These include:

- antacids, medicines used to treat indigestion
- other products containing calcium
- magnesium, iron, aluminium supplements

Check with your doctor or pharmacist if you are not sure

whether you are taking any of these products.

These medicines may be affected by risedronate or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor may have more information on medicines to be careful with or avoid while taking risedronate.

How to take this medicine

Follow carefully all directions given to you by your doctor.

Their instructions may be different to the information in this leaflet.

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

How much to take

Your doctor will tell you how many tablets you will need to take. This depends on your condition and whether or not you are taking any other medicines.

For osteoporosis, the usual dose is either:

- one 35 mg tablet weekly;
- one 75 mg tablet taken on two consecutive days (two tablets in total) each month; or
- one 150 mg tablet monthly.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

How to take it

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

It is important to take risedronate 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.

When to take it

Risedronate is most effective when your stomach is empty.

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

Risedronate 35 mg

Take your 35 mg risedronate tablet on the same day each week. The tablet should be taken each week. Choose a day of the week that suits you the best.

Risedronate 75 mg

Take your 75 mg risedronate tablet on two consecutive days on the same dates each month. One tablet should be taken on each day, so that two tablets are taken each month. Choose dates in the month that suit you the best.

Risedronate 150 mg

Take your 150 mg risedronate tablet on the same date each month. The tablet should be taken each month. Choose a date in the month that suits you the best.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

Make sure you have enough to last over weekends and holidays.

If you forget to take it

Risedronate 35 mg

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

Return to taking one tablet once a week, as originally scheduled on your chosen day.

Do not take two 35 mg tablets in one day to make up for the dose that you missed.

Risedronate 75 mg

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, then 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, you should wait until when the doses are next due and then continue taking your tablets as normal.

Risedronate 150 mg

If you have forgotten to take your 150 mg tablet, and it is more than 7 days until your next monthly dose is due, then 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 take your missed dose then.

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 (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency Department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking this medicine

Things you must do

- **If you become pregnant while you are using this medicine, tell your doctor.**
- **Tell any other doctors, dentists and pharmacists who are treating you that you are using this medicine.**
- **If you are about to be started on any new medicine, tell your doctor or pharmacist that you are using this medicine.**
- **If you require a dental procedure, tell your dentist that you are taking risedronate. 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.**
- **If you develop thigh, hip or groin pain tell your doctor immediately.**
- **If you are about to have any blood tests, tell your doctor that you are taking this medicine.**
- **Go to your doctor regularly for a check-up.**

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects.
- **If you are going to have surgery, inform your doctor and tell the surgeon or anaesthetist that you are using this medicine.**

Things you must not do

Do not:

- Lie down for 30 minutes after taking risedronate.
- Have any food or drink, except for plain water for 30 minutes after taking risedronate.
- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

Things to be careful of

Be careful while driving or operating machinery until you know how risedronate affects you.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are using this medicine.

Your doctor will decide whether any change in your treatment is needed.

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 if you notice any of the following:

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

These side effects are usually mild.

Tell your doctor as soon as possible 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

If any of the following happen, stop taking your medicine and either 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.

Tell your doctor immediately or go to the Accident and Emergency Department at your nearest hospital if you notice any of the following:

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

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

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

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

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a

window sill or in the car. Heat and dampness can destroy some medicines.

Keep this medicine 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 tells you to stop taking this medicine or they have passed their expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Risedronate looks like

35 mg tablets

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

75 mg tablets

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

150 mg tablets

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

Ingredients

Each tablet contains 35 mg, 75 mg or 150 mg of risedronate sodium as the active ingredient.

It also contains the following inactive ingredients:

- lactose
- crospovidone
- magnesium stearate
- colloidal anhydrous silica
- hypromellose
- hypolose macrogol 8000
- titanium dioxide
- iron oxide red (35 mg and 75 mg only)
- indigo carmine aluminium lake (150 mg only)

- monobasic dehydrate sodium phosphate (150 mg only)
- dibasic sodium phosphate (150 mg only)

This medicine is gluten-free, sucrose-free, tartrazine-free and free of other azo dyes.

APO-Risedronate tablets are available in:

35 mg

Blister packs of 1, 4, 8, 12 and 16 tablets

Bottles of 4, 8, 12 and 30 tablets.

75 mg

Blister packs of 2, 4, 6 and 8 tablets

Bottles of 30 tablets

150 mg

Blister packs of 1, 2, 3 and 4 tablets.

Not all strengths, pack types and/or pack sizes may be available

Australian Registration Numbers

APO-Risedronate 35 mg (blister pack): AUST R 160642

APO-Risedronate 35 mg (bottle): AUST R 160644

APO-Risedronate 75 mg (blister pack): AUST R 181973

APO-Risedronate 75 mg (bottle): AUST R 181977

APO-Risedronate 150 mg (blister pack): AUST R 181970

Sponsor

Apotex Pty Ltd
16 Giffnock Ave
Macquarie Park, NSW 2113
Australia

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This leaflet was prepared in November 2016