

APO-Risedronate Tablets

Risedronate sodium hemipentahydrate

Consumer Medicine Information

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

What is in this leaflet

This leaflet answers some common questions about risedronate. 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 using this medicine against the benefits they expect it will 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 want to read it again.

What this medicine is used for

Risedronate is used to treat osteoporosis, including osteoporosis caused by taking steroids. It is also used to preserve bone mineral density in patients on long term steroid therapy.

Osteoporosis

Throughout life, old bone is broken down and replaced with new bone. After the age of 35, bone loss may occur faster than your body can replace it. Excessive bone loss causes

bones to become thinner and weaker, and therefore more likely to break.

Osteoporosis is a disease that gradually weakens bones. Early osteoporosis may not show symptoms. However, if left untreated, it can result in broken bones. Osteoporosis can also cause back pain, height loss and a curved back.

How it works

Risedronate works by slowing down the process of old bone being removed, which allows the bone-forming cells time to rebuild normal bone. This reverses the progression of osteoporosis by creating stronger bone which is less likely to fracture.

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.

This medicine is not addictive.

There is not enough information to recommend the use of risedronate in children under the age of 18 years.

Before you use this medicine

When you must not use it

Do not use this medicine if you have an allergy to:

- risedronate
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- 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

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).

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it is expired or damaged, return it to your pharmacist for disposal.

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

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have any of the following medical conditions:

- bone and mineral metabolism disturbances (e.g. vitamin D deficiency, parathyroid hormone abnormalities)
- oesophageal problems (e.g. 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 therapy used to treat cancer or taking corticosteroids (e.g. prednisone or cortisone).

Tell your doctor if you are pregnant, plan to become pregnant or are breastfeeding.

Do not take this medicine until you and your doctor have discussed the risks and benefits involved.

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

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

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

They may differ to the information contained in this leaflet.

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

How much to take

The usual dose is either:

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

Choose the day that best fits your schedule.

How to take it

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

Stay upright (sitting, standing or walking around) for at least 30 minutes after swallowing the tablet and until after you have eaten your first food of the day

Do not lie down immediately after swallowing it.

Do not take any food, medicines or drinks other than plain water for 30 minutes during this time.

These actions will help make sure the tablet reaches your stomach quickly and helps avoid irritation to your oesophagus.

When to take it

This medicine should be taken on empty stomach. Food, drinks (other than plain water), and other medicines will lessen the effect of this medicine by interfering with its absorption into the body.

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

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, 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, wait until 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, 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 continue taking your tablets as normal.

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)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much of this medicine.

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

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 become pregnant while you are using this medicine, tell your doctor immediately.

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, such as infection or delayed healing after teeth are pulled out or other work that involves drilling into the jaw.

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

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

Tell your doctor immediately if you develop thigh, hip or groin pain.

If you are going to have surgery, tell the surgeon and anaesthetist that you are using this medicine.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects.

Things you must not do

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

Do not take your medicine to treat any other complaint unless your doctor tells you to.

Do not 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.

Side effects

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

This medicine helps most people with osteoporosis but may have unwanted side effects in some people. 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.

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

The above list includes the more common side effects of this medicine. They are usually mild.

Tell your doctor as soon as possible if you notice any of the following:

- itchiness, skin rash or skin redness, sometimes made worse by sunlight
- blurred vision, eye pain or redness
- difficulty or pain on swallowing; new or worsening heartburn (stop taking the tablets, as this side effect may be due to irritation or ulceration of the food pipe)
- jaw or teeth problems associated with delayed healing and/or infection, often following a tooth extraction or invasive dental work

The above list includes serious side effects that may require medical attention.

If you notice any of the following, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

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

The above list includes very serious side effects. You may need urgent medical attention.

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

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

Storage and disposal

Storage

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

If you take your medicine out of the pack it may not keep well.

Keep your tablets in a cool dry place where the temperature stays 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 the expiry date has passed, ask your pharmacist what to do with any medicine left over.

Product description

What it looks like

35 mg tablets:

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

Blister packs of 1, 4, 8, 12 and 16 tablets. AUST R 160642

Bottles of 4, 8, 12 and 30 tablets. AUST R 160644

75 mg tablets:

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

Blister packs of 2, 4, 6 and 8 tablets. AUST R 181973

Bottles of 30 tablets AUST R 181977

150 mg tablets:

Blue, round, biconvex coated tablets, engraved "APO" on one side, "RIS" over "150" on the other side. Blister packs of 1, 2, 3 and 4 tablets. AUST R 181970

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

Ingredients

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

It also contains the following:

- lactose
- crospovidone
- magnesium stearate
- colloidal anhydrous silica
- hypromellose
- hypromellose
- macrogol 8000
- titanium dioxide
- iron oxide red (35 mg and 75 mg tablets only)
- iron oxide yellow (35 mg tablets only)
- indigo carmine aluminium lake (150 mg tablets only)
- monobasic sodium phosphate dihydrate (150 mg tablets only)
- dibasic sodium phosphate (150 mg tablets only)

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

Sponsor

Apotex Pty Ltd
16 Giffnock Ave
Macquarie Park, NSW 2113
Australia
Tel: (02) 8877 8333
Web: www1.apotex.com/au

APO and APOTEX are registered trademarks of Apotex Inc.

This leaflet was prepared in July 2019.