

Risedronate Sandoz®

risedronate sodium film-coated tablets

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Risedronate Sandoz.

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 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 need to read it again.

WHAT RISEDRONATE SANDOZ IS USED FOR

Risedronate Sandoz is used to treat the following bone diseases:

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

It contains the active ingredient Risedronate sodium. Risedronate sodium belongs to a group of medicines called biphosphonates.

It works directly on your bones to make them stronger and therefore less likely to break or fracture, by slowing down the process of old bone being removed and helping to rebuild bone mass.

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

Your doctor may have prescribed it for another reason.

There is no evidence that Risedronate Sandoz is addictive.

Risedronate Sandoz is available only with a doctor's prescription.

There is not enough information to recommend the use of this medicine for children under the age of 18 years.

BEFORE YOU TAKE RISEDRONATE SANDOZ

When you must not take it

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

- risedronate sodium, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under PRODUCT DESCRIPTION.
- any other similar medicines, such as alendronate, pamidronate or any other biphosphonates.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take this medicine if you are not able to stand or sit upright for at least 30 minutes (see HOW TO TAKE RISEDRONATE SANDOZ).

Do not take this medicine if you are pregnant or are breast feeding.

Do not take this medicine if you have severe kidney problems.

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

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

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 or have had any of the following medical conditions:

- 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 Sandoz.

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

If you have not told your doctor about any of the above, tell him/her before you start taking Risedronate Sandoz.

Taking other medicines

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

Some medicines and Risedronate Sandoz may interfere with each other. These include:

- antacids, medicines used to treat indigestion e.g. Gaviscon®, Mylanta®
- other products containing calcium
- iron supplements.

These medicines may be affected by Risedronate Sandoz 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 and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

HOW TO TAKE RISEDRONATE SANDOZ

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

They may differ from the information contained in this leaflet.

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

How much to take

The standard dose for this medicine is one tablet once a week.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, Risedronate Sandoz may not work as well and your problem may not improve.

How to take it

Take Risedronate Sandoz in the morning, at least 30 minutes before your first meal, drink or medication of the day.

Risedronate Sandoz is effective only if taken when your stomach is empty.

Swallow one tablet whole with a glass of plain water.

It is important to take Risedronate Sandoz with plain water only, not mineral water. Mineral water and other drinks, including fruit juices, coffee and tea, will reduce the effect of Risedronate Sandoz.

Do not chew or suck the tablet.

Take the tablet while sitting or standing upright. Do not lie down immediately after swallowing it.

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

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 the tablet reaches your stomach quickly and helps reduce the potential for irritation to your food pipe (oesophagus).

When to take Risedronate Sandoz

Take Risedronate Sandoz once a week, in the morning, at least 30 minutes before your first meal, drink or medication of the day.

Take it on the same day each week. Choose a day of the week that suits you the best.

How long to take Risedronate Sandoz

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

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

Take your dose as soon as you remember, and continue to take it as you would normally.

Do not take two tablets in one day to make up for the tablet you missed.

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 or New Zealand 0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Risedronate Sandoz.

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 TAKING RISEDRONATE SANDOZ

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Risedronate Sandoz.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you require a dental procedure, tell your dentist that you are taking Risedronate Sandoz. 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 Sandoz.

Tell your doctor if you develop difficulty or pain on swallowing, new or worsening heartburn while taking Risedronate Sandoz.

Tell your doctor if you develop any thigh, hip or groin pain while taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

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

Things you must not do

Do not lie down immediately after taking Risedronate Sandoz. Should you wish to lie down, wait for at least 30 minutes.

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

Do not take Risedronate Sandoz to treat any other complaints unless your doctor tells you to.

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

SIDE EFFECTS

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

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

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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 are mild side effects of the medicine.

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.
- problems with your ear/s including chronic ear infections
- pain, weakness or discomfort in your thigh, hip or groin as this may be an early indication of a possible fracture of the thigh bone.

These are rare side effects of the medicine.

If any of the following happen, stop taking Risedronate Sandoz 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, 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, hair loss.

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

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

Other side effects not listed above may also occur in some people.

AFTER TAKING RISEDRONATE SANDOZ

Storage

Keep your medicine in the original container.

If you take it out of its original container it may not keep well.

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

Do not store Risedronate Sandoz 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 it 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 that is left over.

PRODUCT DESCRIPTION

What it looks like

Risedronate Sandoz 35mg - orange, oval, biconvex film-coated tablet marked 35 on one side.

Available in blister packs of 4 tablets.

Ingredients

Active ingredient:

Risedronate Sandoz 35mg - 35mg
risedronate sodium

Inactive ingredients:

- lactose
- crospovidone
- microcrystalline cellulose
- magnesium stearate
- Opadry Orange (containing hypromellose, titanium dioxide, macrogol, iron oxide yellow, iron oxide red).

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

Supplier/Distributor

Sandoz Pty Ltd
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