

# Risedronate Sandoz®

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using Risedronate Sandoz?

Risedronate Sandoz contains the active ingredient risedronate sodium. Risedronate Sandoz is used to treat bone disease and belongs to a group of medicines called bisphosphonates. For more information, see Section [1. Why am I using Risedronate Sandoz?](#) in the full CMI.

### 2. What should I know before I use Risedronate Sandoz?

Do not use if you have ever had an allergic reaction to risedronate sodium or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.** For more information, see Section [2. What should I know before I use Risedronate Sandoz?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Risedronate Sandoz and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use Risedronate Sandoz?

- For osteoporosis, the usual dose is one 35mg tablet each week.
- Take your Risedronate Sandoz tablet while sitting or standing upright.
- Swallow your Risedronate Sandoz tablet whole with a glass of plain water (at least 120mL). Do not chew, cut, crush or suck the tablet.
- Risedronate Sandoz should be taken in the morning either with or without food. More instructions can be found in Section [4. How do I use Risedronate Sandoz?](#) in the full CMI.

### 5. What should I know while using Risedronate Sandoz?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist and pharmacist who are treating you that you are taking Risedronate Sandoz.</li><li>• If you require a dental procedure tell your dentist that you are taking Risedronate Sandoz. Invasive dental procedures should be avoided where possible.</li><li>• If you develop a toothache, jaw pain, painful exposed bone or swelling, especially following dental work, tell your doctor or dentist immediately.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not lie down for 30 minutes after taking Risedronate Sandoz</li><li>• Do not give Risedronate Sandoz to anyone else, even if they have the same condition as you</li><li>• Do not take Risedronate Sandoz to treat any other complaints unless your doctor or pharmacist tells you to.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful before you drive or use any machines or tools until you know how Risedronate Sandoz affects you.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Tell your doctor if you drink alcohol.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep your tablets in a cool dry place where the temperature stays below 25°C .</li><li>• Keep your tablets in the pack until it is time to take them.</li></ul>

For more information, see Section [5. What should I know while using Risedronate Sandoz?](#) in the full CMI.

### 6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Risedronate Sandoz. Like all medicines, Risedronate Sandoz can have side effects, although not everybody gets them. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# Risedronate Sandoz®

Active ingredient(s): *risedronate sodium*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Risedronate Sandoz. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Risedronate Sandoz.**

Where to find information in this leaflet:

- [1. Why am I using Risedronate Sandoz](#)
- [2. What should I know before I use Risedronate Sandoz?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Risedronate Sandoz?](#)
- [5. What should I know while using Risedronate Sandoz?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using Risedronate Sandoz?

Risedronate Sandoz contains the active ingredient **risedronate sodium**. Risedronate Sandoz belongs to a group of medicines called bisphosphates.

Risedronate Sandoz is used to treat bone disease. Risedronate Sandoz works directly on your bones to make them stronger and therefore less likely to break or fracture.

**Risedronate 35mg weekly is used to treat:**

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

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

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

Therefore Risedronate Sandoz can help reverse the progression of osteoporosis.

## 2. What should I know before I use Risedronate Sandoz?

### Warnings

**Do not use Risedronate Sandoz if:**

- you are allergic to risedronate sodium, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- You are allergic to any other substance, such as foods, preservatives or dyes
- 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)
- you have severe kidney problems
- you are already taking products containing risedronate. You should not be taking both Risedronate Sandoz and any other products containing risedronate to treat your osteoporosis because they contain the same active ingredient
- you are pregnant or breastfeeding.

**Do not use Risedronate Sandoz after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

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

**Check with your doctor if you:**

- have any other 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
- 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 Sandoz. This is especially important if you are receiving medicines or therapy used to treat cancer or taking corticosteroids.
- take any medicines for any other conditions

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### **Pregnancy and breastfeeding**

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known whether Risedronate Sandoz passes into breast milk.

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

If you become pregnant while taking Risedronate Sandoz tell your doctor or pharmacist.

### **3. What if I am taking other medicines?**

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

**Some medicines may interfere with Risedronate Sandoz and affect how it works. These include:**

- Antacids, medicines used to treat indigestion e.g. Gaviscon, Mylanta
- Other products containing calcium
- Iron supplements

You may need to stop taking these products or take them at a different time of day to Risedronate Sandoz.

You can take aspirin while you are being treated with Risedronate Sandoz.

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

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Risedronate Sandoz.**

### **4. How do I use Risedronate Sandoz?**

#### **How much to take / use**

- For osteoporosis, the usual dose is one 35mg tablet once a week.
- Follow the instructions provided and use Risedronate Sandoz until your doctor tells you to stop.
- If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

#### **When to take / use Risedronate Sandoz**

- Risedronate Sandoz should be taken in the morning either with or without food.
- Take your Risedronate Sandoz 35mg tablet on the same day each week. Choose a day of the week that suits you best.

#### **How to take Risedronate Sandoz**

Risedronate Sandoz is most effective when your stomach is empty.

- Take your Risedronate Sandoz 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 Sandoz tablet with a glass of plain water. Do not chew, cut, crush or suck the tablet.

It is important to take Risedronate Sandoz 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 Sandoz.

Continue taking Risedronate Sandoz for as long as your doctor recommends it. Do not stop taking Risedronate Sandoz without checking with your doctor or pharmacist.

#### **If you forget to use Risedronate Sandoz**

Risedronate Sandoz should be used regularly at the same time each week. If you miss your dose at the usual time, just take your tablet on the day you remember (as per the instructions described under ‘When to take/ use Risedronate Sandoz’).

**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 taking your medicine, ask your pharmacist for some hints.**

## If you use too much Risedronate Sandoz

If you think that you have used too much Risedronate Sandoz, you may need urgent medical attention.

### You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26 or New Zealand 0800 POISON or 0800 764766)
- contact your doctor, or
- go to the Emergency Department 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.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while using Risedronate Sandoz?

### Things you should do

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking Risedronate Sandoz.

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.

### Call your doctor straight away if you:

- develop a toothache, jaw pain, painful exposed bone or swelling, especially following dental work
- are about to be started on any new medicine
- become pregnant while taking Risedronate Sandoz
- develop new or unusual pain in your hip or thigh. Rarely, patients have experienced fracture in a specific part of the thigh bone.

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

Remind any doctor, dentist or pharmacist you visit that you are using Risedronate Sandoz.

### Things you should not do

- Do not lie down for 30 minutes after taking Risedronate Sandoz.
- Do not give Risedronate Sandoz to anyone else, even if they have the same condition as you.
- Do not take Risedronate Sandoz to treat any other complaints unless your doctor or pharmacist tells you to.
- Do not stop using this medicine suddenly without checking with your doctor or pharmacist.

## Driving or using machines

**Be careful before you drive or use any machines or tools until you know how Risedronate Sandoz affects you.**

Risedronate Sandoz may cause dizziness in some people.

## Drinking alcohol

**Tell your doctor if you drink alcohol.**

## Looking after your medicine

- 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.

- Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight where the temperature stays below 25°C; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

### Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

## Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"><li>• stomach pain</li><li>• diarrhoea</li><li>• aching muscles, joints or bones</li><li>• headache</li><li>• nausea</li><li>• runny nose</li><li>• sore throat</li><li>• dizziness</li><li>• skin rash or redness of the skin, sometimes made worse by sunlight, itchiness</li><li>• blurred vision, pain or redness in the eyes</li><li>• problems with your jaw or teeth, associated with delayed healing</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p> <p><b>They are generally mild and do not cause patients to stop taking Risedronate Sandoz.</b></p>

and/or infection often following a tooth extraction or invasive dental work <ul style="list-style-type: none"> <li>• difficulty or pain on swallowing*</li> <li>• new or worsening heartburn*</li> </ul>	
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### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• chest pain*</li> <li>• swelling of the face, lips, mouth, throat or tongue</li> <li>• severe skin reactions</li> </ul>	<b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b>

\* 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 or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the New Zealand Pharmacovigilance Centre at <https://nzphvc.otago.ac.nz/reporting/>. By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

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

### What Risedronate Sandoz contains

<b>Active ingredient (main ingredient)</b>	risedronate sodium
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>• crospovidone</li> <li>• microcrystalline cellulose</li> <li>• magnesium stearate</li> <li>• Opadry Orange (containing hypromellose, titanium dioxide, macrogol 400, iron oxide yellow, iron oxide red)</li> </ul>
<b>Potential allergens</b>	<ul style="list-style-type: none"> <li>• sugars as lactose</li> <li>• galactose</li> </ul>

**Do not take this medicine if you are allergic to any of these ingredients.**

### What Risedronate Sandoz looks like

Risedronate Sandoz 35mg – orange, oval, biconvex film-coated tablet marked 35 on one side (Aust R 154854).

Available in blister packs of 4 tablets.

### Who distributes Risedronate Sandoz

Sandoz Pty Ltd

ABN 60 075 449 553

54 Waterloo Road

Macquarie Park, NSW 2113

Tel: 1800 726 369

Novartis New Zealand Limited

PO Box 99102

Newmarket, Auckland 1149

New Zealand

Tel: 0800 354 335

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