

# Actonel<sup>®</sup> EC

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## 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.

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### 1. Why am I using Actonel EC?

Actonel EC contains the active ingredient risedronate sodium. Actonel EC 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 Actonel EC?](#) in the full CMI.

### 2. What should I know before I use Actonel EC?

Do not use if you have ever had an allergic reaction to Actonel EC 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 Actonel EC?](#) in the full CMI.

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

Some medicines may interfere with Actonel EC 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 Actonel EC?

- For osteoporosis, the usual dose is one Actonel EC 35mg enteric-coated tablet once a week
- Take your Actonel EC tablet while sitting or standing upright.
- Swallow your Actonel EC tablet whole with a glass of plain water (at least 120mL). Do not chew, cut, crush or suck the tablet.
- Actonel EC should be taken in the morning either with or without food.

More instructions can be found in Section [4. How do I use Actonel EC?](#) in the full CMI.

### 5. What should I know while using Actonel EC?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor or dentist you visit that you are using Actonel EC.</li><li>• If you require a dental procedure, tell your</li></ul>
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	<p>dentist that you are taking Actonel EC. Invasive dental procedures should be avoided where possible.</p> <ul style="list-style-type: none"> <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>
<p><b>Things you should not do</b></p>	<ul style="list-style-type: none"> <li>● Do not lie down for 30 minutes after taking Actonel EC.</li> <li>● Do not give Actonel EC to anyone else, even if they have the same condition as you.</li> <li>● Do not take Actonel EC to treat any other complaints unless your doctor or pharmacist tells you to.</li> </ul>
<p><b>Driving or using machines</b></p>	<ul style="list-style-type: none"> <li>● Be careful before you drive or use any machines or tools until you know how Actonel 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 30°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 Actonel EC?](#) 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 Actonel EC. Like all medicines, Actonel EC 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.

# Actonel EC<sup>®</sup>

**Active ingredient(s):** *risedronate sodium*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using Actonel EC. **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 Actonel EC.**

**Where to find information in this leaflet:**

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

## 1. Why am I using Actonel EC?

**Actonel EC contains the active ingredient risedronate sodium.** Actonel belongs to a group of medicines called bisphosphonates.

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

## **Actonel EC 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.

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

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

Therefore Actonel EC can help reverse the progression of osteoporosis.

## **2. What should I know before I use Actonel EC?**

### **Warnings**

#### **Do not use Actonel EC if:**

1. you are allergic to risedronate sodium, or any of the ingredients listed at the end of this leaflet.
2. You are allergic to any other substances, such as foods, preservatives or dyes
3. Always check the ingredients to make sure you can use this medicine.

4. are unable to stand or sit upright for at least 30 minutes
5. have a condition called hypocalcaemia (a low level of calcium in the blood)
6. have severe kidney problems
7. are already taking any products containing risedronate. You should not be taking both Actonel EC and any other products containing risedronate to treat your osteoporosis because they contain the same active ingredient
8. you are pregnant or breastfeeding.

### **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 Actonel EC. This is especially important if you are receiving medicines or therapy used to treat cancer or taking corticosteroids, such as prednisone or cortisone
- take any medicines for any other condition



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. Your doctor will discuss the possible risks and benefits of using Actonel EC during pregnancy.

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

Actonel EC 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 Actonel EC 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 and Actonel EC 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

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

You can take aspirin while you are being treated with Actonel EC.

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

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

## **4. How do I use Actonel EC?**

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

- For osteoporosis, the usual dose is one Actonel EC 35mg enteric-coated tablet once a week.
- Follow the instructions provided and use Actonel EC 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 Actonel EC**

- Actonel EC should be taken in the morning either with or without food.
- Take your Actonel EC 35mg Once-a-Week enteric-coated tablet on the same day each week. Choose a day of the week that suits you the best.

- Take your Actonel EC tablet while sitting or standing upright.
- Swallow your Actonel EC tablet whole with a glass of plain water (at least 120mL). Do not chew, cut, crush or suck the tablet.
- 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 important to take Actonel EC with plain water only (at least 120 mL), not mineral water. This will help make sure the tablet reaches your stomach quickly and helps avoid irritation to your oesophagus.

Continue taking Actonel EC for as long as your doctor recommends it.

**Do not stop taking Actonel EC without checking with your doctor or pharmacist.**

## **If you forget to use Actonel EC**

Actonel EC 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 Actonel EC').

**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.**

## **If you use too much Actonel EC**

If you think that you have used too much Actonel EC, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- 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 Actonel EC?**

### **Things you should do**

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking Actonel EC.

If you require a dental procedure, tell your dentist that you are taking Actonel EC. 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:**

- If you develop a toothache, jaw pain, painful exposed bone or swelling, especially following dental work, tell your doctor or dentist immediately.
- If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking Actonel EC.
- become pregnant while taking Actonel EC tell your doctor or pharmacist. If you 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 Actonel EC.

Remind any doctor or dentist you visit that you are using Actonel EC.

### **Things you should not do**

- Do not lie down for 30 minutes after taking Actonel EC.

- Do not give Actonel EC to anyone else, even if they have the same condition as you.
- Do not take Actonel EC to treat any other complaints unless your doctor or pharmacist tells you to.
- Do not stop taking Actonel EC 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 Actonel EC affects you.**

Actonel EC 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 where the temperature stays below 30°C, away from moisture, heat or sunlight; for example, do not store it:

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

Heat and dampness can destroy some medicines

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

**Do not take Actonel EC if the packaging is torn or shows signs of tampering.**

**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.

## **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 and/or infection often following a tooth extraction or invasive dental work</li><li>● difficulty or pain on swallowing*</li><li>● new or worsening heartburn*</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>



## 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>Stop taking Actonel. 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.

**Do not be alarmed by this list of possible side effects.**

You may not experience any of them

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). 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 Actonel EC contains

<b>Active ingredient (main ingredient)</b>	risedronate sodium
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>• disodium edetate</li><li>• microcrystalline cellulose</li><li>• colloidal anhydrous silica</li><li>• sodium starch glycollate type A</li><li>• stearic acid</li><li>• magnesium stearate</li><li>• methacrylic acid ethyl acrylate copolymer (1:1)</li><li>• triethyl citrate</li><li>• purified talc</li><li>• iron oxide yellow</li></ul>

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|  | <ul style="list-style-type: none"><li>• simethicone</li><li>• polysorbate 80</li></ul> |
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**Do not take this medicine if you are allergic to any of these ingredients.**

Actonel EC does not contain sucrose, gluten, tartrazine or any other azo dyes.

## **What Actonel EC looks like**

Actonel EC 35mg Once-a-Week - oval yellow enteric-coated tablet, with EC 35 marked on one side.

The 35mg tablets are supplied in pack sizes of 1, 2#, 4, 10#, 12# and 16# tablets.

# non-marketed presentations

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## **Who distributes Actonel EC**

Actonel EC is supplied in Australia by:

Theramex Australia Pty Ltd

Level 22,

60 Margaret Street,

Sydney NSW 2000

1800 THERAMEX or 1800 843 726

This leaflet was prepared in April 2021.