

Actonel® EC

35mg Once-a-Week Enteric-Coated Tablets

risedronate sodium

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Actonel EC (enteric-coated tablets).

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 Actonel EC against the benefits this medicine is expected to 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 Actonel EC is used for

Actonel EC is used to treat bone disease and belongs to a group of medicines called bisphosphonates.

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.

Do not give Actonel EC to children or adolescents under 18 years of age.

There have been no studies of its effects in this age group.

There is no evidence that Actonel EC is addictive.

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

Before you take Actonel EC

When you must not take Actonel EC

Do not take Actonel EC if you:

- have an allergy to Actonel EC or any of the ingredients listed at the end of this leaflet
- are unable to stand or sit upright for at least 30 minutes
- have a condition called hypocalcaemia (a low level of calcium in the blood)
- have severe kidney problems
- 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

Do not take Actonel EC if you are pregnant.

Actonel EC is not recommended for use during pregnancy, unless you

and your doctor have discussed the risks and benefits involved.

Do not take Actonel EC if you are breastfeeding.

It is not known whether Actonel EC passes into breast milk.

Do not take Actonel EC after the expiry date printed on the pack.

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.

Talk to your doctor or pharmacist if you are not sure whether you should start taking Actonel EC.

Before you start to take it

Tell your doctor or pharmacist if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes

Tell 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.

Tell your doctor or pharmacist if you are breastfeeding or plan to breastfeed.

Tell your doctor if 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 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.

Tell your doctor about any of the above, before you start taking Actonel EC.

Taking other medicines

Tell your doctor or pharmacist 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 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

Check with your doctor or pharmacist if you are not sure whether you are taking any of these products.

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.

How to take Actonel EC

How much to take

For osteoporosis, the usual dose is one Actonel EC 35mg enteric-coated tablet once a week.

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

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

How to take it

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.

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 120mL), not mineral water. This will help make sure the tablet reaches your stomach quickly and helps avoid irritation to your oesophagus.

When to take it

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.

This tablet should be taken each week. Choose a day of the week that suits you the best.

If you forget to take your tablet

If you have forgotten to take your 35mg enteric-coated tablet, just take your tablet on the day you remember (as per the instructions described under 'How to Take it' above).

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.

How long to take it

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 take too much (overdose)

Immediately telephone your doctor or pharmacist or the Poisons Information Centre (13 11 26) or go to accident and emergency 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. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using Actonel EC

Things you must 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.

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 Actonel EC.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking Actonel EC.

If you become pregnant while taking Actonel EC tell your doctor or pharmacist.

If you develop new or unusual pain in your hip or thigh, tell your doctor.

Rarely, patients have experienced fracture in a specific part of the thigh bone.

Things you must 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.

Side Effects

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

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 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 side effects are usually mild.

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

These side-effects are rare.

If any of the following happen, stop taking Actonel EC 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, stop taking Actonel EC and 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

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

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

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

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

You may not experience any of them.

After using Actonel EC

Storage

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.

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Do not store Actonel EC or any other medicine in the bathroom or near a sink.

Do not leave medicines in the car on hot days or on window sills.

Heat and dampness can destroy some medicines.

Keep medicines 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 or pharmacist tells you to stop taking Actonel EC or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

- edetate disodium
- microcrystalline cellulose
- colloidal anhydrous silica
- sodium starch glycollate
- stearic acid
- magnesium stearate
- methacrylic acid ethyl acrylate copolymer
- triethyl citrate
- talc- purified
- iron oxide yellow CI77492
- simethicone
- polysorbate 80

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

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

non-marketed presentations

Australian Registration Numbers:

AUST R 166838

Supplier

Actonel EC is supplied in Australia by:

Teva Pharma Australia Pty Ltd
37 Epping Rd
Macquarie Park, NSW, 2113

Date of Preparation: August 2017

Product description

What Actonel EC looks like

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

Ingredients

Active ingredient:

Each Actonel EC 35mg Once-a-Week tablet contains 35 mg risedronate sodium per tablet

Other inactive ingredients include: