

Actonel[®] EC Combi D

risedronate sodium (enteric-coated), calcium carbonate, cholecalciferol (Vitamin D3)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Actonel EC Combi D.

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 Combi D 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 Combi D is used for

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

Actonel EC Combi D is a combination medicine consisting of risedronate sodium, calcium carbonate and cholecalciferol (Vitamin D3). Each week of therapy includes:

One Actonel EC 35mg Once-a-Week enteric-coated tablet (the small yellow tablet) and 6 sachets containing calcium carbonate 2500mg and cholecalciferol 22mcg (Vitamin D3 880 IU).

The active ingredient in Actonel EC 35mg Once-a-Week enteric-coated

tablets is called risedronate sodium and belongs to a group of medicines called bisphosphonates.

Actonel EC 35mg Once-a-Week enteric-coated tablets are used to treat:

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

The calcium carbonate contained in the sachet helps to supply the calcium your body needs to build new bone.

The cholecalciferol (Vitamin D3) contained in the sachet is an essential nutrient required for calcium absorption.

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

Actonel EC Combi D also helps to rebuild bone mass. This creates stronger bone which is less likely to fracture. Therefore Actonel EC Combi can help reverse the progression of osteoporosis.

Do not give Actonel EC Combi D 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 Combi D is addictive.

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

Before you take Actonel EC Combi D

When you must not take Actonel EC Combi D

Do not take Actonel EC Combi D if:

- you have an allergy to risedronate sodium, calcium carbonate, cholecalciferol, or any of the ingredients listed at the end of this leaflet

- you are unable to stand or sit upright for at least 30 minutes
- you have a condition called hypercalcaemia (a high level of calcium in the blood)
- you have high levels of calcium in your urine
- you have problems with your kidneys eg. kidney stones

Do not take Actonel EC Combi D if you are pregnant.

Actonel EC Combi D is not recommended for use during pregnancy, unless you and your doctor have discussed the risks and benefits involved.

Do not take Actonel EC Combi D if you are breastfeeding.

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

Do not take Actonel EC Combi D 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 and may be harmful.

Do not take Actonel EC Combi D 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 Combi D.

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 Combi D during pregnancy.

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

Tell your doctor if you are planning to have any dental procedures or dental surgery.

Your doctor may suggest you have a dental examination before you start taking Actonel EC Combi D.

Tell your doctor if you have or have had any medical conditions, especially the following:

- kidney problems
- 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 Actonel EC Combi D.

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 Combi D.

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 Combi D 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 Combi D.

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

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

How to take Actonel EC Combi D

How much to take

Your doctor or pharmacist will tell you how to take Actonel EC Combi D.

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

Ask your doctor or pharmacist for help if you do not understand the instructions on the box.

How to take it

DAY 1

Take your Actonel EC 35mg Once-a-Week enteric-coated tablet while sitting or standing upright.

Swallow your Actonel EC 35mg Once-a-Week enteric-coated 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 very important to take the Actonel EC 35mg Once-a-Week enteric-coated tablet 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.

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.

DAYS 2 TO 7

Take one sachet the day after you start taking the Actonel EC 35mg Once-a-Week enteric-coated tablet, for the following 6 days.

The contents of the sachet should be poured into a glass of plain water (approximately 200mL), stirred and drunk immediately once the fizzing has subsided.

The sachet can be taken at any time of the day, with or without food.

Do not take your Actonel EC 35mg Once-a-Week enteric-coated tablet on any day you take a sachet.

The days of the week are printed on each sachet to help you remember to take your medicine.

If you forget to take it

For Actonel EC 35mg Once-a-Week enteric-coated tablets:

If you have forgotten to take your Actonel EC 35mg Once-a-Week enteric-coated tablet, take your tablet on the following day (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. Do not take your Actonel EC 35mg Once-a-Week enteric-coated tablet on any day that you take your sachet.

You should start using a new box every 7th day according to your chosen cycle. Starting with the yellow coloured Actonel EC 35mg Once-a-Week enteric-coated tablet on the weekday you have chosen as Day 1.

For the sachet:

If you forget to take a sachet then just skip that dose and continue taking the next sachet in your pack. Any sachets left in the box after your weekly cycle should be discarded.

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 Combi D for as long as your doctor recommends it.

Do not stop taking Actonel EC Combi D 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 Combi D

Things you must do

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

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

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

If you become pregnant while taking Actonel EC Combi D 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 your Actonel EC tablet.

Do not give Actonel EC Combi D to anyone else, even if they have the same condition as you.

Do not take Actonel EC Combi D to treat any other complaints unless your doctor or pharmacist tells you to.

Do not stop taking Actonel EC Combi D 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 Combi D.

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 Combi D 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 Combi D 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 Combi D

Storage

Keep your tablets and sachet in the pack until it is time to take them.

If you take them out of the pack they may not keep well.

Keep your Actonel EC Combi D packs in a cool dry place where the temperature stays below 25°C.

Do not store Actonel EC Combi D 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 Combi D or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

Product description

What Actonel EC Combi D looks like

Actonel EC 35mg tablet - oval yellow tablet, with EC 35 marked on one side

The calcium carbonate and cholecalciferol sachet contains effervescent granules in individual sachets for daily use.

Actonel EC Combi D pack is supplied in pack sizes of 7#, 14, 21 and 28# days of therapy.

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Ingredients

Each Actonel EC 35mg Once-a-Week enteric-coated tablet contains 35mg of the active ingredient risedronate sodium per tablet. Other inactive ingredients include:

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

Each sachet contains 2500mg calcium carbonate (which is equivalent to 1000mg calcium) and cholecalciferol 22mcg (Vitamin D3 880 IU).

Other inactive ingredients include:

- citric acid - anhydrous
- malic acid
- gluconolactone
- maltodextrin
- sodium cyclamate
- saccharin sodium
- starch - rice

- potassium carbonate
- alpha tocopherol
- soya oil - hydrogenated
- gelatin
- sucrose
- starch - maize
- lemon flavour BSL 119

Actonel EC Combi D does not contain gluten.

Australian Registration Number:

AUST R 166942

Supplier

Actonel EC Combi D is supplied in Australia by:

sanofi-aventis australia pty ltd

12-24 Talavera Road

Macquarie Park NSW 2113

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