Package leaflet: Information for the patient

Actonel® 5 mg

risedronate sodium

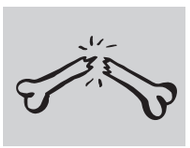
film-coated tablets

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Actonel is and what it is used for

What Actonel is



Actonel belongs to a group of non-hormonal medicines called bisphosphonates which are used to treat bone diseases. It works directly on your bones to make them stronger and therefore less likely to break.

Bone is a living tissue. Old bone is constantly removed from your skeleton and replaced with new bone.

Postmenopausal osteoporosis is a condition occurring in women after the menopause where the bones become weaker, more fragile and more likely to break after a fall or strain. Osteoporosis is more likely to occur in women who have reached the menopause early and also in patients treated long-term with steroids.

The spine, hip and wrist are the most likely bones to break, although this can happen to any bone in your body. Osteoporosis – related fractures can also cause back pain, height loss and a curved back. Many patients with osteoporosis have no symptoms and you may not even have known that you had it.

What Actonel is used for

The treatment of osteoporosis
- in postmenopausal women

The prevention of osteoporosis
- in women with an increased risk of osteoporosis (including low bone mass, early menopause or a family history of osteoporosis).
- in postmenopausal women who have been on high doses of steroid drugs for a long time. It maintains or increases bone mass.

2. What you need to know before you take Actonel

Do not take Actonel

- If you are allergic to risedronate sodium or any of the other ingredients of this medicine (listed in section 6).
- If your doctor has told you that you have a condition called hypocalcaemia (a low blood calcium level).
- If you may be pregnant, are pregnant or planning to become pregnant.
- If you are breast-feeding.
- If you have severe kidney problems.

Warnings and precautions

Talk to your doctor or pharmacist before taking Actonel
- If you are unable to stay in an upright position (sitting or standing) for at least 30 minutes.
- If you have abnormal bone and mineral metabolism (for example lack of vitamin D, parathyroid hormone abnormalities, both leading to a low blood calcium level).
- If you have or have had problems in the past with your oesophagus (the tube that connects your mouth with your stomach). For instance you may have or have had pain or difficulty in swallowing food or you have previously been told that you have Barrett's oesophagus (a condition associated with changes in the cells that line the lower oesophagus).
- If you have been told by your doctor that you have an intolerance to some sugars (such as lactose).
- If you have had or have pain, swelling or numbness of the jaw or a "heavy jaw feeling" or loosening of a tooth.
- If you are under dental treatment or will undergo dental surgery, tell your dentist that you are being treated with Actonel.

Your doctor will advise you on what to do when taking Actonel if you have any of the above.

Children and adolescents

Risedronate sodium is not recommended for use in children below age 18 due to insufficient data on safety and efficacy.

Other medicines and Actonel

Medicines containing one of the following lessen the effect of Actonel if taken at the same time:
- calcium
- magnesium
- aluminium (for example some indigestion mixtures)
- iron.

Take these medicines at least 30 minutes after your Actonel tablet.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Actonel with food and drink

It is very important that you do NOT take your Actonel tablet with food or drinks (other than plain water) so that it can work properly. In particular do not take this medicine at the same time as dairy products (such as milk) as they contain calcium (see section 2, "Other medicines and Actonel").
Take food and drinks (other than plain water) at least 30 minutes after your Actonel tablet.

Pregnancy and breast-feeding

Do NOT take Actonel if you may be pregnant, are pregnant or planning to become pregnant (see section 2, "Do not take Actonel"). The potential risk associated with the use of risedronate sodium (active substance in Actonel) in pregnant women is unknown.
Do NOT take Actonel if you are breast-feeding (see section 2, "Do not take Actonel").

Driving and using machines

Actonel is not known to affect your ability to drive and use machines.

Actonel contains a small amount of lactose (see section 2, "Warnings and precautions").

3. How to take Actonel

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is ONE Actonel tablet (5 mg of risedronate sodium) once a day.

For your convenience, the days of the week are printed on the blister foil to help you remember to take your medicine.

WHEN to take the Actonel tablet

IT IS BEST to take your Actonel tablet at least 30 minutes before the first food, drink (other than plain water) or other medicine of the day.

If in particular instance you are unable to take your Actonel tablet at this time, you may take it on an empty stomach, at the same time every day, in one of the following ways:
- EITHER
  Between meals: at least 2 hours after your last food, drink (other than plain water) or other medicine. Do not eat or drink (other than plain water) for 2 hours after taking the tablet.
- OR
  In the evening: at least 2 hours after your last food, drink (other than plain water) or other medicine of the day. Actonel should be taken at least 30 minutes before going to bed.

Please turn over...

HOW to take the Actonel tablet

- Take the tablet whilst you are in an upright position (you may sit or stand) to avoid heartburn.
- Swallow it with at least one glass (120 ml) of plain water.
- Swallow it whole. Do not suck or chew it.
- Do not lie down for 30 minutes after taking your tablet.

Your doctor will tell you if you need calcium and vitamin supplements, if you are not taking enough from your diet.

If you take more Actonel than you should
If you or somebody else has accidentally taken more Actonel tablets than prescribed, drink one full glass of milk and seek medical attention.

If you forget to take Actonel

If you have forgotten to take your tablet at your regular time, you can take it at the next possible time according to the instruction above (i.e. before breakfast, between meals, or in the evening).

Do not take a double dose to make up for a forgotten tablet.

If you stop taking Actonel
If you stop treatment you may begin to lose bone mass. Please talk to your doctor before you consider stopping treatment.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Actonel and contact a doctor immediately if you experience any of the following:
- Symptoms of a severe allergic reaction such as:
  – Swelling of the face, tongue or throat
  – Difficulties in swallowing
  – Hives and difficulties in breathing
- Severe skin reactions that can include blistering of the skin.

Tell your doctor promptly if you experience the following side effects:
- Eye inflammation, usually with pain, redness and light sensitivity.
- Bone necrosis of the jaw (osteonecrosis) associated with delayed healing and infection, often following tooth extraction (see section 2, "Warnings and precautions").
- Symptoms from oesophagus such as pain when you swallow, difficulties in swallowing, chest pain or new/worsened heartburn.

Unusual fracture of the thigh bone particularly in patients on long-term treatment for osteoporosis may occur rarely. Contact your doctor if you experience 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.

However in clinical studies the other side effects that were observed were usually mild and did not cause the patient to stop taking their tablets.

Common side effects (may affect up to 1 in 10 people)
- Indigestion, feeling sick, stomach ache, stomach cramps or discomfort, constipation, feelings of fullness, bloating, diarrhoea.
- Pain in your bones, muscles or joints.
- Headache.

Uncommon side effects (may affect up to 1 in 100 people)
- Inflammation or ulcer of the oesophagus (the tube that connects your mouth with your stomach) causing difficulty and pain in swallowing (see also section 2, "Warnings and precautions"), inflammation of the stomach and duodenum (bowel draining the stomach).
- Inflammation of the coloured part of the eye (iris) (red painful eyes with a possible change in vision).

Rare side effects (may affect up to 1 in 1,000 people)
- Inflammation of the tongue (red swollen, possibly painful), narrowing of the oesophagus (the tube that connects your mouth with your stomach).
- Abnormal liver tests have been reported. These can only be diagnosed from a blood test.

Very rare (may affect up to 1 in 10,000 people):
- Talk to your doctor if you have ear pain, discharge from the ear, and/or an ear infection. These could be signs of bone damage in the ear.

During post-marketing experience, the following have been reported (unknown frequency):
- Hair loss
- Liver disorders, some cases were severe

Rarely, at the beginning of treatment, a patient's blood calcium and phosphate levels may fall. These changes are usually small and cause no symptoms.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:
United Kingdom
Yellow Card Scheme at: www.mhra.gov.uk/yellowcard
Ireland
HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2;
Tel: +353 1 6764971; Fax: +353 1 6762517.
Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Actonel

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Actonel contains
The active substance is risedronate sodium. Each tablet contains 5 mg risedronate sodium, equivalent to 4.64 mg risedronic acid.

The other ingredients are:
Tablet core: lactose monohydrate (see section 2), crospovidone, magnesium stearate and cellulose microcrystalline.

Film coating: hypromellose, macrogol, hydroxypropylcellulose, colloidal anhydrous silica, titanium dioxide [E171], iron oxide yellow [E172].

What Actonel looks like and contents of the pack
Actonel 5 mg film-coated tablets are oval yellow tablets with the letters "RSN" on one side and "5 mg" on the other side. The tablets are supplied in blister packs of 14, 28 (2x14), 84 (6x14), 98 (7x14) tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
Warner Chilcott UK Limited,
Old Belfast Road,
Millbrook, Larne, County Antrim,
BT40 2SH, United Kingdom

Manufacturer:
Warner Chilcott Deutschland GmbH,
Dr.-Otto-Röhm-Str. 2-4,
64331 Weiterstadt, Germany

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium:	Actonel 5 mg filmomhulde tabletten, Actonel 5 mg comprimé pelliculé, Actonel 5 mg Filmtabletten
France:	Actonel 5 mg comprimé pelliculé
Germany:	Actonel 5 mg Filmtabletten
Ireland:	Actonel 5 mg film-coated tablets
Italy:	Actonel 5 mg compresse rivestite con film
Luxembourg:	Actonel 5 mg comprimé pelliculé,
The Netherlands:	Actonel 5 mg, filmomhulde tabletten
Spain:	Actonel 5 mg comprimidos recubiertos con película
Sweden:	Optinate 5 mg filmdragerade tabletter
United Kingdom:	Actonel 5 mg film-coated tablets

This leaflet was last revised in: January 2016

AAAI0071