

PACKAGE LEAFLET: INFORMATION FOR THE USER

Actonel® Once a Week 35mg Film-coated Tablets

risedronate sodium

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Actonel® Once a Week is and what it is used for
2. Before you take Actonel® Once a Week
3. How to take Actonel® Once a Week
4. Possible side effects
5. How to store Actonel® Once a Week
6. Further information

1. WHAT ACTONEL® ONCE A WEEK IS AND WHAT IT IS USED FOR

What Actonel® Once a Week is

Actonel® Once a Week 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 can also occur in men due to a number of causes including ageing and/or a low level of the male hormone, testosterone.

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® Once a Week is used for

The treatment of osteoporosis

• in postmenopausal women, even if osteoporosis is severe.

It reduces the risk of spinal and hip fractures.

• in men.

2. BEFORE YOU TAKE ACTONEL® ONCE A WEEK

Do NOT take Actonel® Once a Week

- If you are allergic to risedronate sodium or any of the other ingredients of Actonel® Once a Week (see section 6, "What Actonel® Once a Week contains")
- 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.

Take special care and talk to your doctor BEFORE you start taking Actonel® Once a Week

- 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 had problems in the past with your oesophagus (the tube that connects your mouth with your stomach). For instance you may have had pain or difficulty in swallowing food.
 - 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® Once a Week.
- Your doctor will advise you on what to do when taking Actonel Once a Week if you have any of the above.

Children

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

Taking other medicines

Medicines containing one of the following lessen the effect of Actonel® Once a Week 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® Once a Week tablet. Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Taking Actonel® Once a Week with food and drink

It is very important that you do NOT take your Actonel® Once a Week 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, "Taking other medicines").

Take food and drinks (other than plain water) at least 30 minutes after your Actonel® Once a Week tablet.

Pregnancy and breast-feeding

Do NOT take Actonel® Once a Week if you may be pregnant, are pregnant or planning to become pregnant (see section 2, "Do not take Actonel® Once a Week").

The potential risk associated with the use of risedronate sodium (active substance in Actonel® Once a Week) in pregnant women is unknown.

Do NOT take Actonel® Once a Week if you are breast-feeding (see section 2, "Do not take Actonel® Once a Week").

Actonel® Once a Week should only be used to treat postmenopausal women and men.

Driving and using machines

Actonel® Once a Week is not known to affect your ability to drive and use machines.

Important information about some of the ingredients of Actonel® Once a Week

Actonel® Once a Week contains a small amount of lactose (see section 2, "Take special care and talk to your doctor before you start taking Actonel® Once a Week").

3. HOW TO TAKE ACTONEL® ONCE A WEEK

Dosage

Always take Actonel® Once a Week exactly as your doctor has told you. You should check with your doctor if you are not sure.

Usual dose:

Take ONE Actonel® Once a Week tablet (35 mg of risedronate sodium) once a week. Choose one day of the week that best fits your schedule. Every week, take the Actonel® Once a Week tablet on your chosen day.

For your convenience, so that you take your tablet on the right day every week, there is a feature included with the Actonel® Once a Week pack:

There are boxes/spaces on the back of the blister card. Please mark the day of the week you have chosen to take your Actonel® Once a Week tablet. Also, write in the dates you will take the tablet.

WHEN to take the Actonel® Once a Week tablet

Take your Actonel® Once a Week tablet at least 30 minutes before the first food, drink (other than plain water) or other medicine of the day.

HOW to take the Actonel® Once a Week 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® Once a Week than you should

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

If you FORGET to take Actonel® Once a Week

If you have forgotten to take your tablet on your chosen day, take it on the day you remember. Return to taking one tablet once a week on the day the tablet is normally taken.

Do NOT take two tablets in one day to make up for the tablet you missed.

If you STOP taking Actonel® Once a Week

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Actonel Once a Week 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 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, "Take special care and talk to your doctor before you start taking Actonel® Once a Week").
- Symptoms from oesophagus such as pain when you swallow, difficulties in swallowing, chest pain or new or worsened heartburn.

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.

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.

Common side effects (less than 1 in 10 but more than 1 in 100 patients)

- 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 (less than 1 in 100 but more than 1 in 1,000 patients)

- 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, "Take special care and talk to your doctor before you start taking Actonel® Once a Week"), 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 (less than 1 in 1,000 patients)

- 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.

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.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE ACTONEL® ONCE A WEEK

- Keep out of the reach and sight of children.

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

- This medicinal product does not require any special storage conditions.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Actonel® Once a Week contains

The active substance is risedronate sodium. #

Each tablet contains 35 mg risedronate sodium, equivalent to 32.5mg risedronic acid.

The other ingredients are:

Tablet core: lactose monohydrate, crospovidone, magnesium stearate and cellulose microcrystalline.

Film coating: hypromellose, macrogol, hypromellose and silicon dioxide, titanium dioxide [E171], iron oxide yellow [E172], iron oxide red [E172].

What Actonel® Once a Week looks like and contents of the pack

Actonel® Once a Week 35 mg film-coated tablets are oval light-orange tablets with the letters "RSN" on one side and "35 mg" on the other side. The tablets are supplied in blister packs of 4 tablets.

Parallel Product Authorisation Holder and Manufacturer:

Parallel Product Authorisation Holder

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue,
Northwest Business Park
Ballycoolin, Dublin 15
Ireland

Manufacturer

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

Repackaged by

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue,
Northwest Business Park
Ballycoolin, Dublin 15
Ireland

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

Austria: Actonel einmal wöchentlich 35 mg Filmtabletten

Belgium: Actonel 35 mg Wekelijks filmomhulde tabletten,
Actonel 35 mg hebdomadaire comprimé pelliculé,
Actonel 35 mg Wöchentlich Filmtabletten

Cyprus: Actonel 35 mg επικαλυμμένα με λεπτή υμένιο δισκία

Czech Republic: Actonel 35 mg potahované tablety

Denmark: Optinate Septimum filmover trukne tabletter

Estonia: Actonel 35 mg OAW, õhukese polümeerikattega tabletid

Finland: Optinate Septimum 35 mg kalvopäällysteiset tabletit

France: Actonel 35 mg comprimé pelliculé

Germany: Actonel einmal wöchentlich 35 mg Filmtabletten

Greece: Actonel OAW / «μία φορά την εβδομάδα»

Hungary: Actonel 35 mg filmtableta

Iceland: Optinate 35 mg filmuhúðaðar töflur

Ireland: Actonel Once a Week 35mg film coated tablets

Italy: Actonel 35 mg compressa rivestita con film

Latvia: Actonel 35 mg apvalkotās tabletes

Luxembourg: Actonel 35 mg Wekelijks filmomhulde tabletten,
Actonel 35 mg hebdomadaire comprimé pelliculé,
Actonel 35 mg Wöchentlich Filmtabletten

Malta: Actonel "Once a Week" 35mg film-coated tablet

The Netherlands: Actonel Wekelijks 35 mg, filmomhulde tabletten

Poland: Actonel, 35 mg tabletki powlekane

Portugal: Actonel 35 mg comprimidos revestidos por película

Slovakia: Actonel 35 mg filmom obalené tablety

Slovenia: Actonel enkrat tedensko 35 mg filmsko obložena tableta

Spain: Actonel 35 mg comprimidos recubiertos con película

Sweden: Optinate Septimum 35 mg filmdragerade tabletter

United Kingdom: Actonel Once a Week 35mg film-coated tablets

For more information on osteoporosis contact:

The Irish Osteoporosis Society,

33 Pearse Street, Dublin 2.

Helpline phone number: 1890252751

Office phone: 01 6774267

Fax: 01 6351698

E-mail: info@irishosteoporosis.ie

Date of Last Revision: March 2018