



Actonel®

Once-a-Week

risedronate sodium/
risédronate monosodique

35mg

Film-coated tablet/
Comprimé pelliculé

sanofi aventis

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.

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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 have had an allergic reaction in the past 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.

Taking other medicines

Very few medicines are known to interfere with the effect of Actonel Once-a-Week.

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.

Tell your doctor promptly if you experience the following side effects:

- Allergic reactions such as hives, swelling of the face, lips, and tongue and/or throat possibly causing difficulty in breathing or swallowing.
- Severe skin reactions involving blisters under the skin.
- 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").

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 (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.

Changes in the number of some types of white blood cells have also been measured in blood tests. 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 pack.

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 32.5 mg risedronic acid.

The other ingredients are:

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

Film coating: hypromellose, macrogol 400, hydroxypropyl cellulose, macrogol 8000 and silicon dioxide, titanium dioxide [E171], ferric oxide yellow [E172], ferric 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 1, 2, 4, 10, 12 or 16 tablets. Not all pack sizes may be marketed.

Manufacturer

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For sanofi-aventis

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