



Mineral water and other drinks, including fruit juices, coffee and tea, will reduce the effect of Actonel.

Take your Actonel tablet while sitting or standing upright.

**Do not lie down for 30 minutes 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 stay upright until after you have eaten your first food of the day. This will help make sure the tablet reaches your stomach quickly and helps avoid irritation to your esophagus.

Do not chew or suck the tablet!

While under treatment with this medicine, be sure to eat a diet rich in calcium and vitamin D, such as dairy products. Do not retain this medicine in your mouth longer than the time needed for swallowing it. Non-compliance with the instructions for taking the medication may increase the risk of injury to the esophagus.

**If you have accidentally taken a higher dose, or if a child has accidentally swallowed the medicine,** go immediately to a hospital emergency room and bring the medicine package with you.

**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.

**If you forget to take the medicine at the scheduled time** and the time remaining until the next monthly administration is more than 7 days - take a tablet the next morning.

**If you forget to take the medicine at the scheduled time** and the time remaining until the next monthly administration is 7 days or less - do not take this dose but wait and take the tablet on the day preset by you as the next monthly administration date.

Persist the treatment as recommended by the physician.

If you are not sure what you should do, ask your physician or pharmacist.

If you have trouble remembering to take your medicine, consult your pharmacist.

**How long you should take the medicine**

Continue taking Actonel for as long as your physician recommends it.

Do not stop treatment with this medicine without consulting the physician or the pharmacist.

Do not take medicines in the dark! Check the label and the dose each time you take the medicine. Wear glasses if you need them.

If you have any further questions regarding the use of this medicine, consult the physician or the pharmacist.

#### **4. Side effects**

As with any medicine, Actonel Once a Month 150 mg may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not experience any of them.

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

**Stop treatment and refer immediately to the physician or to hospital emergency room if you notice:**

- Symptoms of severe allergic reaction, such as:
  - Swelling of the face, lips, mouth, throat or tongue
  - Difficulties in swallowing
  - Hives and difficulty in breathing
- Severe skin reactions that can include blistering of the skin

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

**Stop treatment and refer immediately to the physician if you notice:**

Rare side effects:

- Difficulty or pain in swallowing
- Chest pain
- New or worsening heartburn

These side effects may be due to irritation or ulceration of the esophagus. They may worsen if you continue taking the tablets.

- Inflammation of the stomach or duodenum
- Inflammation of the tongue (red and swollen, possibly painful), narrowing of the esophagus
- Sensitivity of the lining of the small intestine, of the tongue, the eyes

**Refer immediately to the physician if you notice:**

Rare side effects:

- Skin irritation or rash, sometimes become worse by sunlight exposure or itchiness
- Eye inflammation, usually accompanied by pain, redness and sensitivity to light, blurred vision
- Jaw or teeth problems, associated with delayed healing and/or infection, usually following tooth extraction or invasive dental procedure (see section "Warnings")

Unusual fracture of the thigh bone, particularly in patients on long-term treatment for osteoporosis, may occur rarely. Contact the physician if you experience pain, weakness or discomfort in the thigh, hip or groin area as these signs may indicate a fracture of the thigh bone.

**Additional side effects**

**Tell your physician or pharmacist if you notice any of the following:**

- Gastrointestinal disturbances, such as: indigestion, abdominal pain or discomfort, diarrhea, bloating, nausea and constipation, feeling of fullness
- Runny nose
- Sore throat
- Dizziness
- Muscle, bone or joint pains
- Headache
- Abnormal liver tests have been reported. Can only be diagnosed from blood tests

Side effects reporting during marketing (unknown frequency):

- Hair loss
- Liver disorders, severe in some cases

If a side effect occurs, if any side effect gets worse, or if you suffer from a side effect not mentioned in the leaflet, you should consult the physician.

#### **5. How to store the medicine?**

- Avoid poisoning! This medicine and any other medicine should be kept in a close place out of the reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the physician.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Even if stored as recommended, medicines may be kept for a limited period only. Please note the expiry date of this medicine! In case of doubt, consult the pharmacist who dispensed the medicine to you.
- Store at a temperature below 25°C.
- Store in the original package.
- Do not store Actonel in the bathroom or near a sink. Heat and dampness can destroy medicines.
- Do not leave medicines in the car or on window sills on hot days.
- Do not use the medicine if the packaging is torn or shows signs of tampering.
- Do not discard the medicine to the wastewater or household waste. Consult the pharmacist about how to dispose of the medicine. These measures will help in environmental protection.

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, please ask your physician.

#### **6. Additional information**

**In addition to the active ingredient, the medicine also contains:**

Microcrystalline Cellulose, Crospovidone, Hypromellose, Magnesium stearate, Macrogol 400, Hydroxypropylcellulose, Macrogol 8000, Colloidal anhydrous silica, Titanium Dioxide (E171), Indigo Carmine (E132).

**What does the medicine look like and what are the contents of the package:**

Oval film-coated light blue tablet, with RSN marked on one side and 150 marked on the other. Marketed in packs of 1,2,3,4 tablets. Not all packs may be marketed.

**License Holder:** Abic Marketing Ltd., POB 8077, Netanya 42504.

**Manufacturer:** Warner Chilcott Deutschland GmbH, Germany.

**Registration number of the medicine in the National Drug Registry of the Ministry of Health:** 143-43-32995.

This leaflet was checked and approved by the Ministry of Health in: September 2015.