



Actonel[®] plus Calcium D

35 mg + 1000 mg/880 IU

film-coated tablets + effervescent granules

Risedronate sodium + calcium/colecalciferol

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 plus Calcium D is and what it is used for.
2. Before you take Actonel plus Calcium D.
3. How to take Actonel plus Calcium D.
4. Possible side effects.
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1. WHAT ACTONEL PLUS CALCIUM D IS AND WHAT IT IS USED FOR

What Actonel plus Calcium D is

A combination medicine packed as weekly units each containing 1 tablet of Actonel and 6 sachets of calcium/vitamin D₃.

[○ Actonel tablets](#)

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

[□ Calcium/vitamin D₃ sachets](#)

The sachets contain calcium/vitamin D₃ effervescent granules which provide the calcium and the vitamin D₃ that your body may need to harden new bone.

What Actonel plus Calcium D is used for

The treatment of osteoporosis, even if severe, in **post-menopausal women** who also need daily **calcium and vitamin D₃ supplementation** as assessed by their doctor. It reduces the risk of spinal and hip fractures.

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.

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. Many patients with osteoporosis have no symptoms and you may not even have known that you had it.

2. BEFORE YOU TAKE ACTONEL PLUS CALCIUM D

Do NOT take Actonel plus Calcium D

- If you are **allergic** to risedronate sodium, calcium carbonate, vitamin D₃, peanut or soya or any of the other ingredients of Actonel plus Calcium D (see section 6, "What Actonel plus Calcium D contains").
- If your doctor has told you that you have a condition called: **hypocalcaemia** (a low blood calcium level), **hypercalcaemia** (a high blood calcium level), **hypercalciuria** (a high calcium level in the urine), **hypervitaminosis D** (a high blood vitamin D level).
- If you may be **pregnant**, are pregnant or planning to become pregnant.
- If you are **breast feeding**.
- If you have **severe kidney problems**, including kidney stones.

Take special care and talk to your doctor BEFORE you start taking Actonel plus Calcium D

- 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.
- If you have a condition called sarcoidosis (an immune system disorder mainly affecting the lungs, which causes shortness of breath and cough).
- If you are already taking supplements of vitamin D.
- 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 plus Calcium D.

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

Taking other medicines

[○ Actonel tablets](#)

Medicines containing one of the following lessen the effect

of the Actonel tablet 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.

[□ Calcium/vitamin D₃ sachets](#)

Medicines containing calcium/vitamin D₃ are known to interfere with the following:

- digitalis (used to treat heart disorders)
- tetracycline antibiotics
- steroids (such as cortisone)
- sodium fluoride (used to strengthen the tooth enamel)
- thiazide diuretics (used to remove water from the body by increasing urine production)
- cholestyramine (used to treat high blood cholesterol levels)
- laxatives (such as paraffin oil).

If you are taking any of the above-mentioned medicines, your doctor will give you further instructions.

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 plus Calcium D with food and drink

[○ Actonel tablets](#)

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 the tablet 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 tablet.

[□ Calcium/vitamin D₃ sachets](#)

Do NOT take the dissolved calcium/vitamin D₃ granules at the same time as foods containing high amounts of oxalic acid (spinach and rhubarb) or phytic acid (whole cereals).

Take the dissolved granules at least 2 hours after eating such foods.

Pregnancy and breast-feeding

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

Do NOT take Actonel plus Calcium D if you are breast-feeding (see section 2, "Do not take Actonel plus Calcium D").

Driving and using machines

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

Important information about some of the ingredients of Actonel plus Calcium D

The tablets contain lactose. The effervescent granules contain sorbitol, sucrose and soya-bean oil (see section 2, "Take special care and talk to your doctor before you start taking Actonel plus Calcium D" and "Do not take Actonel plus Calcium D").

The calcium/vitamin D₃ granules contain potassium (163 mg per sachet). This should be taken into consideration if you have a reduced kidney function or are on a controlled potassium diet.

3. HOW TO TAKE ACTONEL PLUS CALCIUM D

Actonel plus Calcium D is a weekly therapy presented in a box containing 1 tablet (in a blister) and 6 sachets containing effervescent granules that should be taken in a special way. Every weekly box has dosing instructions on the back.

Dosage

Always take Actonel plus Calcium D exactly as your doctor has told you. You should check with your doctor if you are not sure.

Usual dose:

Weekly cycle:

- **Day 1: Actonel tablet (light-orange tablet)**
Take ONE Actonel tablet once a week.
Choose one day of the week that best fits your schedule. This will be your Day 1 of the weekly cycle. Every week, take the Actonel tablet on your chosen Day 1.
- **Days 2 to 7: Calcium/vitamin D₃ sachets (effervescent granules)**
Beginning on the day after the Actonel tablet has been taken.
Take ONE sachet of calcium/vitamin D₃ granules each day for the next 6 days.

Every 7 days start a new weekly box. You should begin a new box by taking the Actonel tablet on your chosen Day 1.

Do NOT take your Actonel tablet and the sachet on the same day.

WHEN to take the Actonel tablet

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

HOW to take Actonel plus Calcium D

[○ Actonel tablets](#)

- 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.

[□ Calcium/vitamin D₃ sachets](#)

Pour the content of the sachet into a glass of plain water and stir. Wait until the fizzing has subsided, then drink the solution.

If you take MORE Actonel plus Calcium D than you should

[○ Actonel tablets](#)

If you have taken more **tablets** than you should, or if children have been taking medicine by accident, drink one full **glass of milk** and **seek medical attention**.

[□ Calcium/vitamin D₃ sachets](#)

If you have taken more sachets than you should, or if children have been taking medicine by accident, please contact your doctor.

If you FORGET to take Actonel plus Calcium D

[○ Actonel tablets](#)

If you have forgotten to take your tablet on your chosen day (Day 1):

1. Take it on the day you remember. Do NOT take two tablets in one day to make up for the tablet you missed.
2. On the following day take your calcium/vitamin D₃ sachet. Do NOT take your Actonel tablet and the sachet on the same day.
3. Continue taking one sachet each day until the end of the weekly cycle.
4. Discard any remaining sachets in the box at the end of the weekly cycle.

Then start a new weekly cycle: take one Actonel tablet once a week on your chosen Day 1.

[□ Calcium/vitamin D₃ sachets](#)

If you have forgotten to take a calcium/vitamin D₃ sachet:

1. Take it on the day you remember. Do NOT take the sachet on the same day as the Actonel tablet. Do NOT take two sachets on the same day.
2. Continue taking one sachet each day until the end of the weekly cycle.
3. Discard any remaining sachets in the box at the end of the weekly cycle.

If you STOP taking Actonel plus Calcium D

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 plus Calcium D can cause side effects, although not everybody gets them.

[○ Actonel tablets](#)

Stop taking Actonel and contact a doctor immediately

if you experience any of the following:

- Symptoms characteristics of severe tissue swelling (angioedema reactions)
 - Swelling of face, tongue or throat
 - Difficulties in swallowing
 - Hives and difficulties in breathing
- Severe skin reactions involving blisters under the skin.

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

- Eye inflammation, usually with pain, redness and light sensitivity.
- Jaw bone problems 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").

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 plus Calcium D"), 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.

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.

[□ Calcium/vitamin D₃ sachets](#)

Uncommon side effects (less than 1 in 100 but more than 1 in 1,000 patients)

- Hypercalcaemia (a high blood calcium level, with potential symptoms of excessive thirst, loss of appetite, fatigue and in severe cases irregular heart beat), hypercalciuria (a high calcium level in the urine).

Rare side effects (less than 1 in 1,000 patients)

- Constipation, bloating, nausea, abdominal pain, diarrhoea.
- Skin reactions such as itching, rash and hives.

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 PLUS CALCIUM D

- Keep out of the reach and sight of children.
- Do not use this medicine after the expiry date which is stated on the cartons after EXP. 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 plus Calcium D contains

[○ Film-coated tablets](#)

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].

[□ Effervescent granules sachets](#)

The active substances are calcium carbonate and colecalciferol (vitamin D₃). Each sachet of effervescent granules contains 2500 mg calcium carbonate, equivalent to 1000 mg calcium and 22 micrograms (880 International Units [IU] of colecalciferol (vitamin D₃).

The other ingredients are: anhydrous citric acid, malic acid, gluconolactone, maltodextrin, sodium cyclamate, saccharin sodium, lemon flavouring (contains sorbitol [E420], mannitol [E421], gluconolactone, dextrin, acacia, lemon oils and lime flavour), rice starch, potassium carbonate, α-tocopherol, soya-bean oil (hydrogenated), gelatin, sucrose, maize starch.

What Actonel plus Calcium D looks like and contents of the pack

The combination pack is constituted of an outer carton pack containing weekly unit(s) (carton boxes).

Each weekly unit contains:

- one film-coated tablet which is an oval light-orange tablet with the letters "RSN" on one side and "35 mg" on the other side, packaged in a blister card.
- 6 sachets of effervescent granules of calcium and vitamin D₃.

Pack sizes: 1, 2, 4, 12 (3x4) and 16 (4x4) weekly units.

Not all pack sizes may be marketed.

Manufacturer

Procter & Gamble Pharmaceuticals – Germany GmbH, Dr.-Otto-Röhm-Str. 2–4, 64331 Weiterstadt, Germany

For sanofi-aventis

This leaflet was last approved in: 2007-07-13