Package leaflet: Information for the patient

Actonel® Plus Ca & D

35mg film-coated tablets + 1000 mg/880 IU effervescent granules

risedronate sodium + calcium/colecalciferol

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 Plus Ca & D is and what it is used for

What Actonel Plus Ca & D is
A combination medicine packed as weekly units each containing 1 tablet of Actonel and 6 sachets of calcium/vitamin D_3.

○ *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.
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-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.

○ *Calcium/vitamin D_3 sachets*

The sachets contain calcium/vitamin D_3 effervescent granules which provide the calcium and the vitamin D_3 that your body may need to harden new bone.

What Actonel Plus Ca & D is used for
The treatment of osteoporosis, even if severe, in **postmenopausal women** who also need daily **calcium and vitamin D_3 supplementation** as assessed by their doctor. It reduces the risk of spinal and hip fractures.

2. What you need to know before you take Actonel Plus Ca & D

Do not take Actonel Plus Ca & D
- If you are **allergic** to risedronate sodium, calcium carbonate, vitamin D_3, peanut or soya 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), **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.

Warnings and precautions
Talk to your doctor or pharmacist before taking Actonel Plus Ca & 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 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.
- 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 Ca & D.

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

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

Other medicines and Actonel Plus Ca & D

○ *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 D_3 sachets*

Medicines containing calcium/vitamin D_3 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.
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Actonel Plus Ca & 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, "Other medicines and Actonel Plus Ca & D"). Take food and drinks (other than plain water) at least 30 minutes after your Actonel tablet.

○ *Calcium/vitamin D_3 sachets*

Do NOT take the dissolved calcium/vitamin D_3 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 Ca & D if you are pregnant, think you may be pregnant, or planning to have a baby (see section 2, "Do not take Actonel Plus Ca & 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 Ca & D if you are breast-feeding (see section 2, "Do not take Actonel Plus Ca & D").

Driving and using machines
Actonel Plus Ca & D is not known to affect your ability to drive and use machines.

Actonel tablets contain lactose
The effervescent granules contain sorbitol, sucrose and soya-bean oil (see section 2, "Warnings and precautions" and "Do not take Actonel Plus Ca & D"). The calcium/vitamin D_3 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 Ca & D

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

Recommended 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 D_3 sachets (effervescent granules)*

Beginning on the day after the Actonel tablet has been taken, Take ONE sachet of calcium/vitamin D_3 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 Ca & 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 D_3 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 Ca & 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 D_3 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 Ca & 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 D_3 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 D_3 sachets*

If you have forgotten to take a calcium/vitamin D_3 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 Ca & D

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.

○ *Actonel tablets*

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, "Warnings and precautions").
- Symptoms from oesophagus such as pain when you swallow, difficulties in swallowing, chest pain or new or 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.

During post-marketing experience, the following have been reported:

- Very rare: 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.
- 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.

○ *Calcium/vitamin D_3 sachets*

Uncommon side effects (may affect up to 1 in 100 people)

- 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 (may affect up to 1 in 1,000 people)

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

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via 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 Plus Ca & D

- 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, blister and sachet 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 Plus Ca & 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 (see section 2), crospovidone A, magnesium stearate and cellulose microcrystalline.
Film coating: hypromellose, macrogol, hydroxypropylcellulose and silicon dioxide, titanium dioxide [E171], iron oxide yellow [E172], iron oxide red [E172].

- *Effervescent granules sachets*

The active substances are calcium carbonate and colecalciferol (vitamin D_3). Each sachet of effervescent granules contains 1000 mg calcium (as 2500 mg calcium carbonate) and 22 micrograms (880 International Units [IU]) of colecalciferol (vitamin D_3).
The other ingredients are: citric acid anhydrous, malic acid, gluconolactone, maltodextrin, sodium cyclamate, saccharin sodium, sorbitol [E420], mannitol [E421], dextrin, acacia, natural lemon oils, natural lime flavour, rice starch, potassium carbonate, all-rac-α-tocopherol, soya-bean oil (hydrogenated), gelatin, sucrose, maize starch.

What Actonel Plus Ca & 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 D_3.

Pack size: 4 weekly units

Manufacturer: Warner Chilcott Deutschland GmbH, Dr.-Otto-Röhm-Str. 2-4, 64331 Weiterstadt, Germany or Hermes Pharma GmbH, Allgau 36, 9400 Wolfsberg, Austria.

Product procured from within the EU, repackaged and distributed by the Parallel Product Authorisation Holder: PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.

PPA number - 465/305/1
Actonel is a registered trademark of Warner Chilcott Company, LLC

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

Belgium:	**Actonel Combi D** 35 mg + 1000 mg / 880 IE filmomhulde tabletten + bruisgranulaat, 35 mg +1000 mg / 880 UI comprimé pelliculé et granules effervescents en sachet-dose, 35 mg + 1000 mg / 880 I.E. Filmtabletten + Brausegranulat
France:	**Actonel combi** 35 mg + 1000 mg / 880 UI comprimé pelliculé et granulés effervescents en sachet dose
Germany:	**Actonel plus Calcium D** 35 mg + 1000 mg / 880 I.E. Filmtabletten + Brausegranulat
Ireland:	**Actonel Plus Ca & D** 35 mg film-coated tablets + 1000 mg / 880 i.u. effervescent granules
Lithuania:	**Actonel Combi** 35 mg plėvele dengtos tablets + 1000 mg / 880 TV šnypščiosios granules
Luxembourg:	**Actonel Combi D** 35 mg + 1000 mg / 880 UI comprimé pelliculé et granulés effervescents en sachet dose
Malta:	**Actonel Plus Ca & D** 35 mg film-coated tablets + 1000 mg / 880 i.u. effervescent granules
The Netherlands:	**Actokit D** 35 mg + 1000 mg / 880 IE filmomhulde tabletten + bruisgranulaat
Slovenia:	**Actonel Combi** 35 mg + 1000 mg / 880 IE filmsko obložena tableta + šumeča zrnca
Sweden:	**Optinate Plus Ca &D** 35 mg + 1000 mg / 880 IE filmdragerade tabletter + brusgranulat
United Kingdom:	**Actonel Combi** 35 mg film-coated tablets + 1000 mg / 880 IU effervescent granules

This leaflet was last revised in March 2020.