

Package leaflet: Information for the patient

Optinate Combi D 1000 mg/880 IU effervescent granules + 35 mg gastro-resistant tablet

calcium/cholecalciferol + risedronate sodium

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 [Invented name] is and what it is used for
2. What you need to know before you take [Invented name]
3. How to take [Invented name]
4. Possible side effects
5. How to store [Invented name]
6. Contents of the pack and other information

1. What [Invented name] is and what it is used is used for

[Invented name] is a combination medicine containing gastro-resistant tablets of risedronate sodium and sachets containing calcium/vitamin D₃. These medicines are used to treat bone disease (osteoporosis) in postmenopausal women at risk of fractures. It reduces the risk of spinal and hip fractures. Many patients with bone disease have no symptoms and you may not even know that you have it.

This medicine is given to patients for whom the amount of calcium and vitamin D₃ included is considered to provide adequate supplementation for treatment of bone disease (osteoporosis).

Risedronate sodium tablets

Risedronate belongs to a group of non-hormonal medicines called bisphosphonates. It works directly on your bones to make them stronger and therefore less likely to break.

Calcium/vitamin D₃ sachets (effervescent granules)

The sachets contain calcium/vitamin D₃. The active substance in vitamin D₃ is known as cholecalciferol. The calcium helps to harden new bone and the vitamin D₃ helps to increase the uptake of the calcium after swallowing the medicine.

2. What you need to know before you take [Invented name]

Do not take [Invented name]:

- If you are allergic to risedronate sodium, calcium, vitamin D3 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 have severe kidney problems, including kidney stones (nephrolithiasis)

Warnings and precautions

Talk to your doctor or pharmacist before and while you are taking [Invented name] if you:

- are unable to stay in an upright position (sitting or standing) for at least 30 minutes.
- have abnormal bone and mineral metabolism (for example lack of vitamin D₃, parathyroid hormone abnormalities: both leading to a low blood calcium level).
- have or have had problems with your oesophagus (the tube that connects your mouth with your stomach), e.g. if you have or have had pain, difficulty in swallowing food or 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).
- have ear symptoms, including chronic ear infections.
- have any thigh, hip or groin pain.
- have had or have pain, swelling or numbness of the jaw or a “heavy jaw feeling” or loosening of a tooth.
- are already taking other vitamin D containing medicines.
- are under dental treatment or will undergo dental surgery, tell your dentist that you are being treated with risedronate or other medicines containing calcium or vitamin D₃.
- have problems with your kidneys.
- find it difficult to move around.

Your doctor will advise you on what to do when taking [Invented name] if you have any of the above.

Children and adolescents

[Invented name] is not recommended for use in children below 18 due to insufficient data on safety and efficacy.

Other medicines and [Invented name]

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Medicines containing one of the following lessen the effect of [Invented name] if taken at the same time:

Risedronate sodium tablets

- calcium
- magnesium
- aluminium (for example some indigestion mixtures)
- iron
- esomeprazole

Calcium/vitamin D₃ sachets

- digitalis (used to treat heart disorders)
- tetracycline antibiotics

- systemic corticosteroids (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, tell your doctor.

Take these medicines at a different time of day to your [Invented name]

[Invented name] with food and drink

Risedronate sodium tablets

The tablets **should** be taken immediately after breakfast.

Do not take the tablet at the same time as dairy products (such as milk) (see section 2, “Other medicines and [Invented name]”).

Calcium/vitamin D3 sachets

Do NOT take the dissolved calcium/vitamin D3 at the same time as foods containing high amounts of oxalic acid (spinach and rhubarb) or phytic acid (whole cereals). Take the sachets at least 2 hours after eating these foods.

Pregnancy and breast-feeding

[Invented name] should only be used by postmenopausal women. If you are pregnant or breast-feeding or think you may be pregnant, talk to your doctor for advice before taking these medicines. It must not be used during pregnancy or while breastfeeding.

Driving and using machines

[Invented name] is not known to affect your ability to drive and use machines.

Risedronate sodium tablets contain sodium

This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially ‘sodium-free’.

Calcium/vitamin D₃ granules contain sorbitol, sucrose, potassium and sodium

- This medicine contains 1.1 mg sorbitol in each sachet.
- If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine. May be harmful to the teeth.
- This medicine contains 4.2 mmol potassium (163 mg) in each sachet. To be taken into consideration by patients with a reduced kidney function or patients on a controlled potassium diet.
- This medicine contains less than 1 mmol sodium (23 mg) in each sachet, that is to say essentially ‘sodium-free’.

3. How to take [Invented name]

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

[invented name] is a weekly cycle therapy of tablet and sachets containing effervescent granules. The tablet and sachets must be taken in the correct order, as described below.

Recommended dose:

- *Day 1: Risedronate sodium tablets*
Take ONE 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. Take the tablet on your chosen Day 1 every week.
There are specified space on the blister where you may indicate Day 1 as a reminder of the day when to take the tablet each week.
- *Days 2 to 7: calcium/vitamin D₃ sachets (effervescent granules)*
Beginning on the day after the tablet has been taken,
Take ONE sachet of calcium/vitamin D₃ granules each day for the next 6 days.

Every 7 days repeat this sequence of tablet followed by sachets, ensuring you take the tablet on your chosen Day 1.

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

How to take the risedronate sodium tablet

- The tablet is for oral use.
- The medicine should be taken immediately after breakfast. If taken on an empty stomach, there is an increased risk of abdominal pain.
- Take the tablet whilst you are in an upright position (you may sit or stand) to avoid heartburn.
- Swallow the tablet with at least one glass (120 ml) of plain water.
- The tablet must be swallowed whole. Do not suck or chew the tablet.
- Do not lie down for 30 minutes after taking your tablet.

How to take 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 immediately ([see “Invented name] with food and drink”).

If you take more risedronate sodium tablets than you should

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.

If you take more calcium/vitamin D₃ sachets

If you have taken more content from the sachets than you should, or if children have been taking the medicine by accident, please contact your doctor. Symptoms of an overdose may include excessive thirst, nausea, vomiting, constipation, abdominal pain, muscle weakness, fatigue, increased urination and bone pain. In an extreme overdose, it may lead to coma and be life-threatening.

If you forget to take the risedronate sodium tablet

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 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.
5. take your next tablet on your chosen day (Day 1) again.

If you forget to take 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 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 [Invented name]

If you stop treatment you may begin to lose bone mass. 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.

Stop taking [Invented name] and contact a doctor immediately if you experience any of the following:

- Severe allergic reaction with symptoms such as:
 - swelling of the face, tongue, or throat
 - difficulties in swallowing
 - hives and difficulties in breathing
- Severe skin reactions with symptoms such as
 - blistering of the skin, mouth, eyes, and other moist body surfaces (genitals) (Stevens Johnson syndrome)
 - palpable red spots on the skin (leukocytoclastic vasculitis)
 - red rash over many parts of the body and/or loss of the outer layer of the skin (toxic epidermal necrolysis).

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.
- 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.

Other possible side effects:

Risedronate sodium tablets

Common (may affect up to 1 in 10 people):

- Stomach or gut-pain, indigestion, feeling sick, constipation diarrhoea, vomiting
- Pain in your bones, muscles or joints
- Headache

Uncommon (may affect up to 1 in 100 people):

- Influenza
- Decreased number of white blood cells
- Depression
- Dizziness, numbness tingling or burning sensation, decreased sensitivity
- Inflammation of the coloured part of the eye (iris) (red painful eyes with a possible change in

- vision), inflammation of the outermost layer of the eye and the inner surface of the eyelids (conjunctivitis), eye redness, vision blurred
- Hot flush, low blood pressure
- Coughing
- Vertigo
- Inflammation (gastritis) or ulcer in the stomach or gut. Difficulty swallowing, stomach discomfort, gut distension, feeling bloated, blood in the stool and stool leakage. Increased acid in the stomach, burping, refluxes from stomach or gut, haemorrhoids, stomach hernia and heartburn.
- Numbness of mouth, dry mouth, gum inflammation, mouth sores
- Muscle weakness, muscle spasm, back pain, pain in extremity, pain in jaw, joint pain, neck pain
- Kidney stones
- Cyst in the ovary
- Tiredness, chills, flu like illness, pain in the chest, fever pain
- Increased activity of parathyroid gland
- Blood calcium and phosphate level decreased, blood calcium level increased, platelet count decreased, heart rate irregular, urine analysis abnormal

Rare (may affect up to 1 in 1,000 people):

- Narrowing of the oesophagus (the tube that connects your mouth with your stomach), inflammation of the tongue.
- Abnormal liver tests have been reported. These can only be diagnosed from a blood test.
- Fracture of thigh bone

Very rare (may affect up to 1 in 10,000 people):

- Ear pain, discharge from the ear, and/or an ear infection. These could be signs of bone damage in the ear.
- Osteonecrosis of the external auditory canal (bisphosphonate class adverse reaction)

Not known (frequency cannot be estimated from the available data):

- Hair loss
- Liver disorders, some cases were severe
- Inflammation of the coloured part of the eye (iris) (red painful eyes with a possible change in vision).

Calcium/vitamin D₃ sachets

Uncommon (may affect up to 1 in 100 people)

- Hypercalcaemia (a high blood calcium level, with symptoms of excessive thirst, loss of appetite, fatigue and in severe cases irregular heartbeat), hypercalciuria (a high calcium level in the urine, with symptoms of pain in abdomen, nausea and increased thirst).

Rare (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 [the national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Invented name]

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 sachets 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.

Contents of the pack and other information

What [Invented name] contains

Risedronate sodium tablets

The active substance is risedronate sodium. Each gastro-resistant tablet contains 35 mg risedronate sodium (equivalent to 32.5 mg risedronic acid).

The other ingredients are:

Tablet core:

Microcrystalline cellulose E460, colloidal anhydrous silica, disodium edetate, sodium starch glycolate, stearic acid, magnesium stearate E470b.

Enteric coating:

Methacrylic acid - ethyl acrylate copolymer (1:1), triethyl citrate, talc, iron oxide yellow E172, simeticone, polysorbate 80.

Calcium/vitamin D3 effervescent granules sachets

The active substances are calcium carbonate and cholecalciferol (vitamin D₃). Each sachet contains 1000 mg calcium (as 2500 mg calcium carbonate) and 22 micrograms (880 International Units [IU]) of cholecalciferol (vitamin D₃).

The other ingredients are: citric acid, malic acid, gluconolactone, maltodextrin, sodium cyclamate, saccharin sodium, lemon flavour (containing sorbitol), rice starch, potassium carbonate, all-rac-alpha-tocopherol, sucrose, sodium ascorbate, modified starch, triglycerides, medium chain, colloidal anhydrous silica.

What [Invented name] looks like and contents of the pack

Risedronate sodium tablets are oval, yellow gastro-resistant tablets with "EC 35" engraved on one side. The dimensions of the tablet are as follows: width 13 mm, length 6 mm. Tablets are supplied in PVC/aluminium foil blister containing 4 tablets.

The sachets are made of laminated aluminium paper foil and contain white effervescent granules of calcium and vitamin D₃

The combination pack is constituted of a carton pack containing monthly units.

Each monthly unit contains 4 gastro-resistant tablets and 24 sachets of effervescent granules

Pack sizes:

Monthly units: 1 or 3 months.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

<[To be completed nationally]>

Manufacturer:

<[To be completed nationally]>

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