

Package leaflet: Information for the patient

Ridate Plus Ca & D 35 mg film-coated tablets + 1000 mg / 880 IU effervescent tablets 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 Ridate Plus Ca & D is and what it is used for
2. What you need to know before you take Ridate Plus Ca & D
3. How to take Ridate Plus Ca & D
4. Possible side effects
5. How to store Ridate Plus Ca & D
6. Contents of the pack and other information

1. What Ridate Plus Ca & D is and what it is used for

Ridate Plus Ca & D is used to **treat osteoporosis**, even if severe, in women after menopause who also need daily calcium and vitamin D₃ supplementation. This combination medicine reduces the risk of spinal and hip fractures.

a) Risedronate tablets contains 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.

b) Calcium/vitamin D₃ effervescent tablets provide the calcium and the vitamin D₃ that your body may need to harden new bone.

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

Do not take Ridate Plus Ca & D

if you are/have

- **allergic** to risedronate sodium, calcium carbonate, vitamin D₃, soya, peanut or any of the other ingredients of this medicine (listed in section 6)
- **blood calcium levels** which are **below or above normal**
- **urine calcium levels** which are **above normal**
- **blood vitamin D levels** which are **above normal**
- **pregnant**, may be pregnant or planning to become pregnant
- **breast-feeding**
- severe **kidney problems**, including increased levels of calcium in the kidneys, or kidney stones.

Warnings and precautions

Talk to your doctor or pharmacist before taking Ridate Plus Ca & D. Tell your doctor before taking this medicine if any of the following conditions apply to you:

- you are unable to stand or sit upright for at least 30 minutes
- you have abnormal bone and mineral absorption, conversion and/or excretion, for example:
 - lack of vitamin D
 - parathyroid hormone abnormalitiesBoth of which lead to below normal calcium levels.
- you have or have had previous problems with your oesophagus (the tube that connects your mouth with your stomach), such as 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)
- you have sarcoidosis, a disorder mainly affecting the lungs, which causes shortness of breath and coughing
- you are already taking vitamin D
- you had or have pain, swelling or numbness of the jaw, a “heavy jaw feeling” or loosening of a tooth

You may be advised to have a dental check-up before starting the treatment.

- you are under dental treatment or will undergo dental surgery
Tell your dentist that you are being treated with Ridate Plus Ca & D.
- you are undergoing chemotherapy or radiotherapy
- you are taking corticosteroids.

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

Children and adolescents

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

Calcium/vitamin D₃ effervescent tablets are not intended for use in children and adolescents.

Other medicines and Ridate Plus Ca & D

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

a) Medicines containing any of the following reduce the effect of **Risedronate** if taken at the same time:

- calcium
- magnesium
- aluminium, contained for example in medicines to treat heartburn
- iron

Take these medicines at least 30 minutes after your Risedronate tablet.

b) **Calcium/vitamin D₃** is known to affect or be affected by the following medicines:

- digitalis: a medicine to treat heart weakness
- antibiotics such as fluoroquinolones or rifampicin and active substance names ending in “cycline”
- medicines to reduce inflammation or prevent organ transplant rejection, such as cortisone
- sodium fluoride: used to strengthen tooth enamel or to treat osteoporosis
- thiazides diuretics: medicines to increase water output through your kidneys
- cholestyramine: a medicine to reduce blood fat levels
- laxatives, such as paraffin oil
- aluminium, contained for example in medicines to treat heartburn
- orlistat; a medicine to treat obesity
- phenytoin: a medicine to treat epilepsy

- barbiturates: a central nervous system depressant
- iron, zinc or strontium ranelate preparations
- thyroid hormones
- estramustin: a chemotherapy medicine.

Your doctor will give you further instructions, if you take any of the above-mentioned medicines.

Ridate Plus Ca & D with food and drink

a) Do not take your **Risedronate** tablet **with food or drinks**, other than plain water, to ensure that it works properly. This particularly applies to dairy products, such as milk, as they contain calcium, (see section 2, “Other medicines and Ridate Plus Ca & D”).

Food and drinks, other than plain water, may only be taken at least 30 minutes after your Risedronate tablet.

b) Do not take the dissolved **Calcium/vitamin D₃** effervescent tablets with foods containing high amounts of

- oxalic acid, such as spinach and rhubarb, or
- phytic acid, such as whole cereals

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

Pregnancy and breast-feeding

Do not take Ridate Plus Ca & D if you are, may be pregnant or plan to become pregnant. The risk associated with the use of risedronate sodium in pregnant women is unknown.

Do not take Ridate Plus Ca & D if you are breast-feeding.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Ridate Plus Ca & D is not known to affect your ability to drive or use machines.

Ridate Plus Ca & D contain lactose, sucrose, sodium, and sulphites

The Calcium carbonate/vitamin D₃ effervescent tablets

This medicine contains sucrose and lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine contains 96.12 mg sodium (main component of cooking/table salt) in each tablet. This is equivalent to 4.8% of the recommended maximum daily dietary intake of sodium for an adult.

This medicine contains sulphites. May rarely cause severe hypersensitivity reactions and bronchospasm.

Risedronate sodium film-coated tablets

This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

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

3. How to take Ridate Plus Ca & D

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

Ridate Plus Ca & D is a **weekly therapy** of:

- a) 1 Risedronate tablet
- b) 6 Calcium/vitamin D₃ effervescent tablets

The recommended dose per weekly cycle is:

- Day 1
1 Risedronate tablet (orange tablet)
Choose one day of the week that best fits your schedule. This will be “Day 1” of your weekly cycle.
Every week, take the Risedronate tablet on your chosen “Day 1” at the position of the strip which is marked with the corresponding week (e.g. week 1).
- Days 2 to 7
1 Calcium/vitamin D₃ effervescent tablet per day for the next 6 days
Start Calcium/vitamin D₃ intake on the day after the Risedronate tablet has been taken.

Do not take the Risedronate tablet and the Calcium/vitamin D₃ effervescent tablet **on the same day**.

Every 7 days start a new weekly box beginning with the Risedronate tablet on your chosen “Day 1”.

Method of use

Oral use.

a) Take your **Risedronate** tablet whole:

- **in the morning** at least 30 minutes before your first food, drink or other medicine
- whilst you sit or stand, to avoid heartburn
- with at least one glass of plain water

Do not lie down for 30 minutes after taking your tablet. Swallow it whole, do not suck or chew the tablets.

b) Take the **Calcium/vitamin D₃ effervescent** tablet after dissolving it in a glass of water.

If you take more Ridate Plus Ca & D than you should

a) Drink **one glass of milk** and seek medical attention if you have taken more **Risedronate** tablets than prescribed or if children have been taking this medicine by accident.

b) Please contact your doctor if you have taken more **Calcium/vitamin D₃ effervescent** tablets than you should or if children have been taking this medicine by accident.

If you forget to take Ridate Plus Ca & D

a) If you have forgotten to take your **Risedronate** tablet on your chosen day “Day 1”:

1. Take it on the day you remember. Do not take two Risedronate tablets in one day to make up for the tablet you missed.
2. On the following day take your Calcium/vitamin D₃ effervescent tablet. Do not take your Risedronate tablet and the effervescent tablet on the same day.
3. Continue taking one Calcium/vitamin D₃ effervescent tablet each day until the end of the weekly cycle.
4. Discard any remaining calcium/vitamin D tablets in the box at the end of the weekly cycle. Then start a new weekly cycle: take one Risedronate tablet once a week on your chosen “Day 1”.

b) If you have forgotten to take a **Calcium/vitamin D₃ effervescent** tablet:

1. Take it on the day you remember, but do not take two effervescent tablets on the same day. Do not take the effervescent tablet on the same day as the Risedronate tablet.
2. Continue taking one effervescent tablet each day until the end of the weekly cycle.

3. Discard any remaining calcium/vitamin D effervescent tablets in the box at the end of the weekly cycle.

If you stop taking Ridate 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.

a) Possible side effects caused by Risedronate

Stop taking Risedronate and contact a doctor immediately if you experience any of the following:

- Symptoms of **severe allergic reaction** such as:
 - swelling of face, tongue or throat
 - difficulties in swallowing
 - hives and difficulties in breathing
- severe **skin reactions** 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).

Inform your doctor immediately if you have:

- 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 difficulty and pain 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.

Bone necrosis of the external auditory canal (osteonecrosis) mainly in patients on long-term treatment for osteoporosis may occur very rarely. 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.

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, may affect up to 1 in 10 people

- indigestion, feeling sick, stomach pain, stomach cramps or discomfort, constipation, feelings of fullness, bloating, diarrhoea
- pain in your bones, muscles or joints
- headache.

Uncommon, may affect up to 1 in 100 people

- inflammation or ulcer of the gullet (the tube that connects your mouth with your stomach) causing difficulty and pain in swallowing, inflammation of the stomach and the first part of the small bowel immediately beyond the stomach

- inflammation of the coloured part of the eye (iris) causing red, painful eyes and visual disturbances.

Rare, may affect up to 1 in 1,000 people

- tongue inflammation with swelling and possible pain
- narrowing of the gullet
- abnormal liver blood tests
- reduced blood calcium and phosphate levels.

These changes are usually small, occur at the beginning of treatment and cause no symptoms.

During post-marketing experience, the following have been reported (**Not known:** frequency cannot be estimated from the available data)

- hair loss
- liver disorders, some cases were severe.

b) Possible side effects caused by Calcium/vitamin D₃

In **very rare** cases (may affect up to 1 in 10,000 people), **serious allergic reaction** which causes difficulty in breathing or dizziness, swelling of the face or throat has been reported. **Contact a doctor immediately** if you experience any of above mentioned symptoms.

Uncommon, may affect up to 1 in 100 people

- blood calcium levels above normal
Symptoms are excessive thirst, loss of appetite, fatigue and in severe cases irregular heartbeat.
- urine calcium levels above normal.

Rare, may affect up to 1 in 1,000 people

- allergic reactions
- constipation, wind, nausea, vomiting, abdominal pain, diarrhoea
- skin reactions such as itching, rash and hives.

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

- milk-alkali syndrome (also called Burnett's Syndrome and usually only seen when excessive amounts of calcium have been ingested), symptoms are frequent urge to urinate, headache, loss of appetite, nausea or vomiting, unusual tiredness or weakness, along with elevated levels of calcium in the blood and kidney impairment.

Special patient group

If you suffer from kidney problems you may get high levels of phosphate in your blood, kidney stones or increased levels of calcium in the kidneys.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system: HPRA Pharmacovigilance; website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ridate 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 after "EXP". The expiry date refers to the last day of that month.

Do not store above 25°C. Store in the original package in order to protect from light and moisture.

Effervescent tablets

Shelf life after first opening: 1 month

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 Ridate Plus Ca & D contains

a) Risedronate film-coated tablets

The active substance is risedronate sodium.

Each film-coated tablet contains 35 mg of risedronate sodium, equivalent to 32.5 mg risedronic acid.

The other ingredients are microcrystalline cellulose, crospovidone, lactose monohydrate, magnesium stearate, hypromellose, macrogol 400, titanium dioxide (E171), iron oxide yellow (E172) and iron oxide red (E172).

b) Calcium/vitamin D₃ effervescent tablets

The active substances are calcium carbonate and colecalciferol (vitamin D₃).

Each effervescent tablet contains:

- 2500 mg calcium carbonate, equivalent to 1000 mg calcium.
- 22 micrograms (880 International Units [IU]) colecalciferol (vitamin D₃).

The other ingredients are citric acid anhydrous, simeticone, gelatine, lactose monohydrate, macrogol 6000, maize starch, methylcellulose, sodium cyclamate, sodium hydrogen carbonate, povidone K25, saccharin sodium, hydrogenated soya oil, sucrose, alpha-tocopherol and orange juice flavour (PHS-133147 containing maltodextrin, orange flavouring substances, hydroxyethyl starch, sodium and sulphites).

What Ridate Plus Ca & D looks like and contents of the pack

a) Risedronate film-coated tablets: oval biconvex, orange, encoded 35 on one side. The film-coated tablets are packed in an aluminium/PVC blister.

b) Calcium/vitamin D₃ effervescent tablets: cylindrical, white or off-white coloured biplanar effervescent tablets with bevel-edges on both sides. The effervescent tablets are packed in a polypropylene tube with polyethylene stopper containing a silica gel desiccant.

Ridate Plus Ca & D is available in packs containing

- 4 film-coated tablets + 24 (2 x 12) effervescent tablets

A single carton box contains both the film-coated tablet blister (placed in a carton box) and the effervescent tablets in tubes for one month use

- 3 x (4 film-coated tablets + 24 (2 x 12) effervescent tablets)

A single carton box contains both the film-coated tablet blister (placed in carton boxes) and the effervescent tablets in tubes for three months use

- 4 x (4 film-coated tablets + 24 (2 x 12) effervescent tablets)

A single carton box contains both the film-coated tablet blister (placed in carton boxes) and the effervescent tablets in tubes for four months use.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers

Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.

Lek Pharmaceuticals d.d., Verovškova 57, 1526 Ljubljana, Slovenia.

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

United Kingdom: Risedronate sodium and Calcium /Cholecalciferol 35 mg + 1000 mg / 880 IU Film coated Tablets + Effervescent Tablets

Ireland: Ridate Plus Ca & D 35 mg film-coated tablets + 1000 mg / 880 IU effervescent tablets

This leaflet was last revised in 09/2020.