Package leaflet: Information for the patient

Ridate Once a Week 35 mg film-coated tablets

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 Ridate is and what it is used for
Ridate is used to **treat osteoporosis** in
- women after the menopause, even if osteoporosis is severe.
  It reduces the risk of spinal and hip fractures.
- men at high risk of fractures.

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

2. What you need to know before you take Ridate
Do not take Ridate if you
- are **allergic** to risedronate sodium or any of the other ingredients of this medicine (listed in section 6)
- have blood **calcium levels** which are **below normal**
- may be **pregnant,** are pregnant or planning to become pregnant
- are **breast-feeding**
- have severe **kidney problems**.

Warning and precautions
Talk to your doctor before taking this medicine if any of the following conditions apply to you:
- if you are unable to stand or sit upright for at least 30 minutes
- if you have abnormal bone and mineral absorption, conversion and/or excretion, for example:
  - lack of vitamin D
  - parathyroid hormone abnormalities

  Both of which lead to below normal calcium levels.
- 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 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).
- had or have pain, swelling or numbness of the jaw, a “heavy jaw feeling” or loosening of a tooth
- under dental treatment or will undergo dental surgery
  Tell your dentist that you are being treated with Ridate.
- you have been told by your doctor that you have an intolerance to some sugars (such as lactose).

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

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

Medicines containing any of the following reduce the effect of Ridate 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 Ridate tablet.

Ridate with food and drink
Do not take your Ridate tablet **with food or drinks** other than plain water so that it can work properly. This applies particularly to dairy products, such as milk, as they contain calcium.

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

Pregnancy and breast-feeding
Do not take Ridate if you may be pregnant, are pregnant or plan to become pregnant.

The risk associated with the use of risedronate sodium in pregnant women is unknown.
Do not take Ridate if you are breast-feeding.

Ridate should only be used to treat postmenopausal women and men.

Ask your doctor or pharmacist for advice before taking any medicines.

Driving and using machines
Ridate is not known to affect your ability to drive or use machines.

Ridate contains lactose and sodium
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before you take this medicine.
This medicine contains less than 1 mmol (23 mg) sodium per film-coated tablet, that is to say essentially ‘sodium-free’.

3. How to take Ridate

Dosage
Always take Ridate exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The recommended dose is 1 tablet, once a week.

Choose one day of the week that best fits your schedule. Every week, take the Ridate tablet on your chosen day.

Method of use
Take your 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 (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.

Your doctor will tell you if you need calcium and vitamin supplements.

Duration of use
Please talk to your doctor before you consider stopping treatment. This will be **decided by** your **doctor**.

If you take more Ridate than you should
Drink one glass of milk and inform your doctor if you have taken more tablets than prescribed.

If you forget to take Ridate
If you have forgotten to take your tablet on your chosen day, take it on the day you remember. Return to taking one tablet once a week on the day the tablet is normally taken.

Do not take two tablets in one day to make up for the tablet you missed.

If you stop taking Ridate
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.

Stop taking Ridate and contact a doctor immediately if you experience any of the following:
- symptoms of a **severe allergic reaction** such as
  - swelling of face, lips, tongue, throat and/or neck
  - difficulties in swallowing
  - difficulties in breathing
  - hives, skin rash
- 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 caused by inflammation of small blood vessels (leukocytoclastic vasculitis)
  - red rash over many parts of the body and/or loss of the outer layer of skin (toxic epidermal necrolysis).

Inform your doctor immediately if you have:
- eye inflammation, usually with pain, redness and light sensitivity
- degeneration of the jaw bone associated with delayed healing and infection, often following tooth extraction
- difficulty and pain in swallowing, chest pain, or new or worsened heartburn.

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

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

During post-marketing experience, the following have been reported (unknown frequency)
- Hair loss
- Liver disorders, some cases were severe.

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 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 Ridate
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 blister, bottle and carton after 'EXP'. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Shelf life after first opening:
Bottles: 6 months

Do not throw away 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 contains
- The active substance is risedronate sodium. Each film-coated tablet contains 35 mg risedronate sodium, equivalent to 32.5 mg risedronic acid.
- The other ingredients are in the tablet core microcrystalline cellulose, crospovidone, lactose monohydrate, magnesium stearate; in the film coating hypromellose, macrogol 400, titanium dioxide (E171), ferric oxide yellow (E172), ferric oxide red (E172).

What Ridate looks like and contents of the pack
Oval, orange, rounded on the upper and lower side, marked with '35' on one side.

The film-coated tablets are packed in PVC/Alu blisters and inserted in a carton, or are packed in HDPE-bottles with a polyethylen closure.

Pack sizes:
Blister: 1, 2, 4, 10, 12, 16, 28, 84 film-coated tablets
Bottle: 1, 2, 4, 10, 12, 16, 28, 84 film-coated tablets

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.
Lek S.A., ul. Domaniewska 50 C, 02-672 Warszawa, Poland.
Lek Pharmaceuticals d.d., Trimlini 2D, 9220 Lendava, Slovenia.
S.C. Sandoz S.R.L., 7A Livezeni Street, 540472, Targu Mures, Jud Mures, Romania.

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

Austria:	Risedronat Hexal einmal wöchentlich 35 mg Filmtabletten
Germany:	Risedron-HEXAL 35 mg einmal wöchentlich Filmtabletten
Ireland:	Ridate Once a Week 35 mg film-coated tablets

This leaflet was last revised in 09/2019.