Package leaflet: Information for the user

Ranitic 150 mg & 300 mg Film-coated tablets

ranitidine (as hydrochloride)

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1 What Ranitic is and what it is used for

Ranitidine belongs to a group of medicines called histamine (H2) antagonists. These medicines reduce the amount of acid in your stomach.

This medicine is used:
For adults
- to heal ulcers in the stomach or duodenum
- to prevent the recurrence of ulcers in the stomach or duodenum (when they are a side effect of some medicines)
- to treat inflammation of the gullet (oesophagus) caused by reflux of gastric acid (reflux oesophagitis usually with heartburn)
- to treat a disease in which the stomach produces too much acid (Zollinger-Ellison syndrome)
- to treat other conditions where reduction of acid in the stomach is likely to be beneficial
- to treat post-operative ulcer.

For children (3 to 18 years)
- for the short term treatment of ulcers in the stomach or duodenum
- to treat inflammation of the gullet (oesophagus) caused by reflux of gastric acid (reflux oesophagitis usually with heartburn).

2 What you need to know before you take Ranitic

Do not take Ranitic:
• if you are allergic to ranitidine or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Ranitic
- if you suffer from kidney disease because this is important for your doctor in order to give you the right dose
- before starting treatment with ranitidine, your doctor must have already ascertained that the stomach or duodenal ulcer is not malignant
- if you are elderly, have chronic lung disease, diabetes or a weak immune system as there is an increased risk of developing pneumonia
- if you are taking medicines for arthritis such as aspirin or ibuprofen, especially if you have been told you have a peptic ulcer (gastric or duodenal ulcer)
- you should see your doctor regularly if you are on long term treatment
- if you suffered in the past from a disease that involves blood problems (porphyria).

Do not smoke. Smoking increases the amount of acid produced by the stomach and will aggravate your condition.

Other medicines and Ranitic
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. It is especially important to mention to your doctor if you are also taking:
- diazepam (medicine for anxiety)
- lidocaine (a local anaesthetic)
- phenytoin (medicine for epilepsy)
- theophylline (medicines for asthma)
- ketoconazole (used to treat fungal infections of the skin or nails)
- glipizide (medicine for diabetes)
- midazolam, triazolam (sedatives): the effect of these medicines can be intensified
- propranolol, procainamide and N-acetylprocainamide (medicines for heart problems)
- gefitinib (used in chemotherapy treatment)
- delaviridine and atazanavir (antiviral medicines)
- anticoagulants (medicines to thin your blood, e.g. warfarin)
- sucralfate (another product used for e.g. stomach or duodenal ulcers): the uptake of ranitidine in the blood (and thus its effect) may be reduced. This medicine must therefore be taken about 2 hours after ranitidine.
- non-steroidal anti-inflammatory (NSAID) medicines (for pain and inflammation)
- if you are taking erlotinib, a drug used for the treatment of certain types of cancer, talk to your doctor before you take Ranitic. Ranitidine contained in Ranitic may decrease the amount of erlotinib in your blood and your doctor may need to adjust your treatment if it is used while you are receiving erlotinib.

Pregnancy, breast-feeding and fertility
Only use this medicine during pregnancy after consulting your doctor.

Ranitidine is excreted in the breast milk. Therefore, breast-feeding is not recommended while taking this medicine.

Driving and using machines
No influence on the ability to drive or use machines is expected. However, very rare side effects (e.g. headache, dizziness, confusion and blurred vision) might affect these abilities.

Ranitic contains lactose and sodium
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

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

3 How to take Ranitic

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

The recommended dosage in adults, the elderly and adolescents (12 years and over):

For duodenal or stomach ulcer:
- 150 mg in the morning and 150 mg in the evening or a single dose of 300 mg at night. If necessary the dose can be raised to 300 mg twice daily.
- Duration of treatment: 4 weeks, but can be extended to 8 weeks. For ulcers following NSAID therapy 8–12 weeks treatment may be necessary.

To prevent NSAID associated duodenal ulcers:
- 150 mg in the morning and 150 mg in the evening with NSAID therapy or a single dose of 300 mg at night.

For inflammation of the oesophagus through reflux of gastric acid:
- 150 mg in the morning and 150 mg in the evening or a single dose of 300 mg in the evening
- Duration of treatment: 8 weeks, but can be extended to 12 weeks
- In moderate to severe cases the dose may be increased to 150 mg four times daily or 300 mg twice daily.

To prevent recurrence of inflammation of the oesophagus:
- 150 mg in the morning and 150 mg in the evening
- Duration of treatment: according to the doctor's instructions.

Patients with Zollinger-Ellison syndrome:
- Initial dosage: 150 mg in the morning, 150 mg in the afternoon and 150 mg in the evening
- If necessary, the daily dose can be raised to 6 g.

Usual dosage in children (aged 3 to 11 years and over 30 kg of weight):
For the treatment of stomach or duodenal ulcers:
- The recommended oral dose is 2-4 mg per kg bodyweight 2 times per day with a maximum dose of 300 mg per day split into 2 separate doses
- Duration of treatment: 4 weeks, but can be extended to 8 weeks.

For inflammation of the oesophagus through reflux of gastric acid:
- The recommended oral dose is 2.5 – 5 mg per kg bodyweight 2 times per day with a maximum dose of 600 mg per day, split into 2 separate doses.

Dosage in patients with reduced kidney function:
The dose will be reduced by your doctor depending on the extent to which your kidney function is impaired.

Dosage in patients during childbirth:

150 mg at beginning of labour followed by 150 mg every 6 hours. If an emergency general anaesthetic is required, an antacid should be given prior to induction of anaesthesia.

If you take more Ranitic than you should
Do not take more than your doctor tells you to. If you have accidentally taken more than the prescribed dose, go to the nearest hospital casualty department or tell your doctor/pharmacist immediately. Take the container and any remaining tablets or this leaflet with you so the medical staff knows exactly what you have taken.

If you forget to take Ranitic
If you forget to take a dose, take another as soon as you remember, then carry on as before. Do not take a double dose to make up for a forgotten dose.

If you stop taking Ranitic
After a few days you should feel much better but don't stop taking the tablets until your doctor tells you to or the pain and discomfort may return.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects

Tell your doctor straightaway if you have any of the following symptoms of a severe allergic reaction (affecting less than 1 in 1,000 people):
•sudden difficulty in breathing and chest pain
•swelling of the lips, face and neck
•fever
•small lumps or hives
•low blood pressure.

Contact your doctor as soon as possible if you experience any of the following side effects (affecting less than 1 in 10,000 people):
•increased or reduced urine output, pain, fever, nausea, drowsiness caused by kidney problems
•severe pain in the abdomen and back caused by inflammation of the pancreas.

These are all serious side effects. You may need urgent medical attention.

Other possible side effects

Uncommon: may affect up to 1 in 100 people
•stomach pain
•diarrhoea
•constipation
•nausea.

Rare: may affect up to 1 in 1,000 people
•skin rash
•blood tests which show changes in the way the liver is working

•increased serum creatinine, symptoms include feeling dehydrated, fatigue, shortness of breath and confusion.

Very rare: may affect up to 1 in 10,000 people
•slower heartbeat.
•disorders of cardiac conduction (A-V block)
•faster heartbeat
•blurred vision
•uncontrolled movements, this effect is usually reversible
•headache
•dizziness
•confusion, hallucinations, or depression in predominantly the severely ill, elderly and patients with a kidney disorder
•liver inflammation with or without yellowing of the skin or whites of the eyes
•skin rash with pink-red blotches
•hair loss
•muscle pain, joint pain
•enlarged breasts in males and inability to achieve an erection
•inflammation of blood vessels, often as skin rash (vasculitis)
•recurrent infections, severe exhaustion, sore throat, fever or headache which can be caused by changes in blood count, reduction in white blood cells which makes infections more likely, reduction in blood platelets which makes bruising or bleeding more likely, reduction in red blood cells which can make the skin pale and cause weakness.

Not known: frequency cannot be estimated from the available data
• shortness of breath.

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 Ranitic

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.

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 Ranitic contains
The active substance is ranitidine hydrochloride.

Each Ranitic 150 mg Film-coated Tablet contains ranitidine hydrochloride equivalent to 150 mg ranitidine.
Each Ranitic 300 mg Film-coated Tablet contains ranitidine hydrochloride equivalent to 300 mg ranitidine.

The other ingredients are microcrystalline cellulose, calcium hydrogen phosphate dihydrate, maize starch, sodium starch glycolate (type A), magnesium stearate, colloidal anhydrous silica, lactose monohydrate, hypromellose, titanium dioxide (E171), macrogol 4000.

What Ranitic looks like and contents of the pack
Ranitic 150 mg Film-coated Tablets are white to pale yellow, round and biconvex with a score-notch on one side.
Ranitic 300 mg Film-coated Tablets are white to pale yellow and oblong with a score notch on one side.
The scoreline is only to allow breaking for ease of swallowing and not to divide into equal doses.

Aluminium/aluminium blister pack

Ranitic 150 mg is available in cartons containing 10, 20 and 60 tablets.
Ranitic 300 mg is available in cartons containing 10 and 30 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.
Rowa Pharmaceuticals Ltd., Bantry, Co. Cork, Ireland.

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