Package leaflet: Information for the user

Ranitic 75 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.
Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 14 days.

What is in this leaflet:

1 What Ranitic is and what it is used for

Ranitic 75 mg tablets belong to the group of medicines called H_2–receptor antagonists, which work by reducing the amount of acid you produce in your stomach.

Ranitic 75 mg Tablets are indicated for the short-term relief of the symptoms of **acid indigestion** and **heartburn.**
You must talk to a doctor if you do not feel better or if you feel worse after 14 days.

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
If you suffer from the **metabolic disorder** with malfunction of production of red haemoglobin (called **porphyria**) you should not take Ranitic.

Talk to your doctor, pharmacist or nurse before taking Ranitic
- if you have **kidney or liver disease**
- if you have unintended **weight loss** associated with your indigestion symptoms
- if you are **middle-aged or older** and have symptoms of **indigestion** which are new or recently changed
- if you are at risk of or have a history of **peptic ulcer** (gastric or duodenal ulcer)
- if you are taking any **other medicines** either prescribed or bought from the pharmacist
- if you are **receiving medical attention** for any reason
- if you are elderly, have chronic lung disease, diabetes or a weak immune system as there is an increased risk of developing pneumonia

Ranitic may mask the symptoms of a malignant gastric disorder and accordingly delay the required treatment.

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

Children and adolescents
Ranitic is not recommended in children under 16 years.

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

Some medicines can cause problems if you take them with Ranitic:
- **diazepam** (medicine for anxiety)
- **lidocaine** (a local anaesthetic)
- **phenytoin** (medicine for epilepsy)
- **theophylline** (medicines for asthma)
- **propranolol** (medicines for heart problems)
- **anticoagulants** (medicines to thin your blood, e.g. warfarin)
- **acid neutralising medicines or sucralfate** (an ulcer healing drug); Ranitic should be taken at least two hours before such medicines.
- **ketoconazole** (an antifungal medicine)
- **delaviridine** and **atazanavir** (antiviral medicines)
- **gefitinib** (used in chemotherapy treatment)
- **glipizide** (medicine for diabetes)
- **midazolam, triazolam** (sedatives)
- **non-steroidal anti-inflammatory (NSAID) medicines** (for pain and inflammation)

Pregnancy and breast-feeding and fertility
Ranitic should not be used during pregnancy without your doctor's advice.

Ranitic passes into mother's milk. Ranitic should not be used during breast-feeding without your doctor's advice.

Ask your doctor or pharmacist for advice before taking any 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 described in this leaflet or as your doctor or pharmacist or nurse has told you. Check with your doctor or pharmacist or nurse if you are not sure.

The recommended dose is:
Adults (including the elderly) and adolescents (over 16 years):
Take one film-coated tablet whenever the symptoms appear, day or night. Do not take more than two film-coated tablets in 24 hours.
You should not take Ranitic for more than 2 weeks continuously. If the symptoms deteriorate or persist after 2 weeks, consult your doctor.

Children and adolescents under 16 years:
Do not give Ranitic tablets to children under 16 years.

Mode of administration:
Take the film-coated tablets whole with a sufficient quantity of liquid (e.g. one glass of water) irrespective of meals.

If you take more Ranitic than you should:
If you have accidentally taken too many Ranitic tablets, contact your doctor or pharmacist immediately.

If you forget to take Ranitic:
Do not take a double dose to make up for a forgotten tablet.

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.

If you have any of the following symptoms soon after taking Ranitic tablets, STOP taking the tablets and tell your doctor immediately:
- hypersensitivity disorders: skin rash with severe itching and formation of small lumps (urticaria), accumulation of liquid in tissue (angioneurotic oedema), fever, bronchospasm, low blood pressure, chest pain
- life-threatening (anaphylactic) shock

Uncommon: may affect up to 1 in 100 people
- stomach pain
- diarrhoea
- constipation

- nausea

Rare: may affect up to 1 in 1,000 people
- blood tests which show changes in the way the liver is working
- skin rash
- increased serum creatinine, symptoms include feeling dehydrated, fatigue, shortness of breath and confusion

Very rare: may affect up to 1 in 10,000 patients
- recurrent infections, severe exhaustion, sore throat, fever or headache which can be caused by serious changes in blood counts (agranulocytosis/ pancytopenia), sometimes with bone marrow changes (bone marrow hypoplasia or aplasia)
- reduction in the number of white blood cells or the number of blood platelets in the blood
- confusion (reversible)
- depression
- hallucinations
- headache, sometimes severe
- dizziness
- uncontrolled movements (reversible)
- blurred vision (reversible)
- slower heartbeat (bradycardia)
- disorders of cardiac conduction (A-V block)
- faster heartbeat
- diffuse pains due to inflammation of blood vessels
- inflammation of the pancreas
- liver inflammation with or without yellowing of the skin or whites of the eyes
- skin rash with red (moist) irregular skin eruptions (erythema multiforme)
- hair loss
- muscle pain
- pain of a joint
- inflammation of the kidneys
- reversible sexual inability (impotence)
- swollen or tender breasts in men

Not known: frequency cannot be estimated from the available data
- dyspnoea.

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.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

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 packaging 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 tablet contains ranitidine hydrochloride equivalent to ranitidine 75 mg.

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, yellow ferric oxide (E172).

What Ranitic looks like and contents of the pack
The film-coated tablets are yellow, round and biconvex with a one-sided score-notch. The scoreline is only to allow breaking for ease of swallowing and not to divide into equal doses.

Aluminium/aluminium blister pack

Cartons containing 7, 14 and 28 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturer
Salutas Pharma GmbH, Otto-von-Guericke Allee 1, 39179 Barleben, Germany.
Rowa Pharmaceuticals Ltd., Bantry, Co. Cork, Ireland.

This leaflet was last revised in November 2018.

I.M. L/55c 11-18