

Package leaflet: Information for the user

Ranitidine 75 mg film-coated tablets Ranitidine

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

1. What Ranitidine is and what it is used for

Ranitidine 75 mg film-coated tablets belong to a group of medicines called histamine H₂ antagonists. H₂ antagonists temporarily reduce the amount of acid produced in the stomach so that heartburn and gastric reflux no longer occur. There is still plenty of acid to digest your food.

You can take Ranitidine 75 mg tablets if you suffer from symptoms that are caused by gastric acid, such as heartburn and acid reflux.

2. What you need to know before you take Ranitidine

Do not take Ranitidine tablets

- If you have been shown to be allergic (hypersensitive) to ranitidine or any of the other ingredients of this medicine (listed in section 6).
- If you are under 16 years.

Warnings and precautions

- if you have a kidney or liver disorder. It may be necessary to adjust the dose if your kidney function is impaired.
- if you are undergoing regular medical follow-up.
- if you are middle-aged or elderly and are experiencing gastric symptoms for the first time or if the symptoms are increasing.
- if you are using medicines prescribed or self prescribed by a doctor.
- if you have gastric symptoms and are losing weight.
- if you are using strong painkillers and have previously had a stomach ulcer or if you have an increased risk of stomach ulcer.
- if you have previously had an acute episode of a metabolic disease, the symptoms of which include skin abnormalities (porphyria).

Consult your doctor if any of the above warnings applies to you, or has done so in the past.

Other medicines and Ranitidine

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Avoid taking these tablets at the same time as:

- If the use of Erlotinib is considered during treatment with Ranitidine, it should be used in a staggered manner; i.e. Erlotinib must be taken at least 2 hours before or 10 hours after ranitidine dosing.
- There is a potential decrease of cyanocobalamine absorption when administered in a long-term manner with ranitidine, resulting in a vitamin B12 deficiency.
- if you are using this medicine at the same time as theophylline (an anti-asthma drug); your theophylline dose may need to be adjusted .
- Lidocaine, a local anaesthetic
- Propranolol, procainamide or n-acetylprocainamide, for heart problems
- Diazepam, for worry or anxiety problems
- Phenytoin, for epilepsy
- Warfarin, for thinning your blood
- Caution should be exercised in case of simultaneous administration with atazanavir or delaviridine, for treating HIV infection or gefitinib for lung cancer.
- Antacids and sucralfate (another drug used to treat complaints such as stomach and intestinal ulcers): simultaneous use can reduce ranitidine absorption into the bloodstream (thereby making it less effective). These drugs must therefore be taken about 2 hours after taking ranitidine;
- Medicines whose absorption is dependent on the amount of acid in the stomach may be affected, since ranitidine affects stomach acidity, absorption of this type of substances into the bloodstream may be altered (thereby altering their effect). This can result in either an increase in absorption e.g. triazolam, midazolam, (used to help you sleep and/or relieve anxiety), glipizide (a drug used to reduce blood sugar levels) or decrease in absorption e.g. ketoconazole, itraconazole and Posaconazole (medicines are used to treat fungal infections).

If you use H₂ receptor antagonists, you have an increased risk of developing community-acquired pneumonia. This increased risk has been observed primarily in patients with lung diseases, diabetes, heart failure and in patients with an immunological disorder.

Always consult your doctor or pharmacist if you are not sure.

Ranitidine with food, drink and alcohol

The effect of small amounts of alcohol may be intensified if you are taking ranitidine at the same time. You can use this medicine at any time, with or without food or drink.

Pregnancy

If you are pregnant or intending to become pregnant or are breastfeeding, consult your doctor or pharmacist. No side effects have been observed to date with ranitidine use during pregnancy. Ask your doctor or pharmacist for advice before taking any medicine. Ranitidine should only be used during pregnancy if it is considered necessary.

Breast-feeding

Ranitidine passes into breast milk. It is not known whether this has any effect on the infant and therefore breastfeeding is not recommended if you are using this medicine. Ask your doctor or pharmacist for advice.

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

There are no data on the influence of Ranitidine on the ability to drive and use machines. Should side effects such as confusion, visual disturbances, hallucinations or movement disturbances occur, this ability could be adversely affected.

Ranitidine contains castor oil

It may cause stomach upset and diarrhoea.

3. How to take Ranitidine

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

Method of administration

You can swallow Ranitidine 75 mg tablets with a little water.

The usual dosage

Adults / adolescents (16 years and over)

You can take a tablet as soon as you have symptoms, during the day or at night. Ranitidine 75 mg tablets have an action starting about half an hour after they are taken and lasting for a maximum of 12 hours. Most patients therefore find 1-2 tablets per 24 hours sufficient. A maximum of 4 tablets may be taken in 24 hours. Maximum effect is reached after two hours.

Do not take Ranitidine for longer than 2 weeks at a time

Patients with impaired kidney function:

If your kidney function is impaired, you must consult with your doctor as to whether the dose should be adjusted. It is recommended that no more than 2 tablets be taken during a 24-hour period.

The use of Ranitidine 75 mg in children younger than 16 is not recommended.

If you take more Ranitidine than you should

Contact your doctor or pharmacist immediately.

You might get the following side effects, vomiting, irritability and insomnia in children and drowsiness and nausea in adults.

If you forget to take Ranitidine

Take one tablet as soon as you develop symptoms.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Ranitidine

The use of this medicine can be discontinued suddenly without any adverse effect.

Do not take Ranitidine for longer than 2 weeks at a time.

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 few people can be allergic to some medicines. If any of the following happen, tell your doctor or nurse **immediately**:

- Severe itching of the skin, rash
- swelling of the hands, feet, ankles, face, lips, tongue, mouth or throat, which may cause difficulties in swallowing or breathing
- Chest tightness
- Collapse

Tell your doctor if you notice any of the following:

Uncommon: may affect up to 1 in 10 people)

- stomach pain
- constipation
- feeling sick (nausea) .

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

- skin rash

Rare side effects that may show up in blood tests:

- increase of serum creatinine in blood (kidney function test)
- changes to liver function

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

- Depression
- Confusion, hallucinations (mainly reported in severely ill or elderly patients)
- Blood disorders that may result in unusual tiredness, shortness of breath, more infections than usual, bruising more easily
- Uncontrolled movements
- Heart problems (slow or irregular heart rhythm)
- Inflammation of the blood vessels which may cause reddening of areas of skin, localised pain and tenderness
- Headaches (sometimes severe), dizziness
- Diarrhoea
- Blurred vision
- Inflammation of the pancreas (which may cause severe stomach pain)
- Liver problems which may lead to jaundice (yellow colour of skin and the whites of eyes)
- Red blotches or lumps on the skin, hair loss
- Pain in the joints or muscles
- Kidney problems that may cause changes in the amount and colour of water you pass
- If you are a man, sexual impotence that is normally reversible, tenderness of the breast, breast discharge and/or breast enlargement.

Many of these side effects are reversible and go away once ranitidine treatment is stopped.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRAs 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 Ranitidine

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 and blister. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage condition.

Do not throw away any medicine via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of pack and other information

What Ranitidine contains:

The active substance is ranitidine.
Each tablet contains ranitidine hydrochloride equivalent to 75 mg ranitidine.

The other ingredients are:

Tablet core: microcrystalline cellulose, croscarmellose sodium, anhydrous colloidal silica, purified talc, magnesium stearate.

Tablet coating: hypromellose, castor oil, titanium dioxide (E 171), yellow iron oxide (E172), purified talc.

What Ranitidine looks like and content of the pack.

Ranitidine 75 mg tablets are creamish yellow round, biconvex, film-coated tablets having approximately 7 mm diameter with the inscription "IT" on one side and plain on the other side.

Ranitidine 75 mg tablets are packaged in aluminium blister strips with 6 or 10 tablets. The carton contains 6, 10, 12, 24, 30 or 60 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Accord Healthcare Limited,
Sage House,
319 Pinner Road, Harrow,
Middlesex, HA1 4HF
United Kingdom

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

Country name	Proposed name
The Netherlands	Ranitidine Accord 75 mg filmomhulde tabletten
Estonia	Ranitidine Accord
Ireland	Ranitidine 75 mg film-coated tablets
United Kingdom	Ranitidine 75 mg Film-coated Tablets

The leaflet was last revised in 11/2014.