RANITIDINE 150 mg AND 300 mg TABLETS

PACKAGE LEAFLET: INFORMATION FOR THE USER

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 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 belongs to a group of medicines called histamine H2-antagonists which reduce the amount of acid in your stomach.
Ranitidine is used:
- to treat ulcers of the stomach and duodenum (portion of the small intestine)
- to treat Zollinger-Ellison Syndrome, a condition where the stomach produces too much acid
- to treat a condition called reflux oesophagitis which causes heartburn
- to treat other problems such as indigestion or heartburn where a reduction in stomach acid is required
- to prevent ulcers in the small intestine which are sometimes caused as a side effect of taking non-steroidal anti-inflammatory drugs (sometimes used to treat arthritis e.g. aspirin, ibuprofen, naproxen)
- to prevent bleeding of existing ulcers and gastrointestinal bleeding from stress ulceration in seriously ill patients
- before administration of a general anaesthetic to patients considered to be at risk of Mendelson’s syndrome (e.g. patients during labour), a condition where acid fluid from the stomach is brought up into the windpipe and passes into the lungs.

2. What you need to know before you take Ranitidine

DO NOT take Ranitidine if you:
- if you are allergic (hypersensitive) to ranitidine or any of the other ingredients of ranitidine (listed in section 6).

Warnings and precautions
Tell your doctor before you start to take this medicine if you:
- have ever suffered from porphyria, a deficiency of specific enzymes within the body, causing an increase of substances called porphyrins
- suffer from severe kidney problems
- suffer from any chronic lung disease
- have diabetes
- have a weakened immune system (e.g. due to disease, or due to other medical treatments).

If you are middle aged or older and you have new or recently changed symptoms, you should speak to your doctor, as these may be a sign of a more serious underlying condition requiring different treatment.

If you are taking non-steroidal anti-inflammatory (NSAID) medicines (see “Taking other medicines”), your doctor should monitor you regularly, particularly if you are elderly, or have a history of peptic ulcer.

Other medicines and Ranitidine

Tell your doctor if you are taking any of the following:
- non-steroidal anti-inflammatory (NSAID) medicines, for pain or inflammation, such as aspirin, ibuprofen, or diclofenac
- medicines to thin your blood e.g. warfarin
- procainamide or N-acetylprocainamide (used to treat abnormal heart rhythms)
- triazolam, midazolam (sedative medicines)
- glipizide (used to treat diabetes)
- ketoconazole (used to treat fungal infections)
- atazanavir, delavirdine (used to treat HIV infection)
- gefitinib (used to treat certain types of cancer)
- sucralfate (used to treat certain conditions caused by too much acid being produced in the stomach)

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

Pregnancy and breast-feeding
- If you are pregnant, planning to become pregnant or are breast-feeding, you should not take this medicine unless your doctor advises it is essential.

Driving and using machines
- Ranitidine is not known to affect your ability to drive or operate machinery.

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.

The tablets should be swallowed preferably with a drink of water. The usual dose is

Adults (including the elderly) and adolescents (12 years and over)
- To treat ulcers, reflux oesophagitis, indigestion, dyspepsia or heartburn
  150 mg twice a day, taken in the morning and evening. Sometimes your doctor may advise a single daily dose of 300 mg taken in the evening.
  The exact dose and length of treatment will depend on the condition you are being treated for.
• **Zollinger-Ellison Syndrome**  
The usual starting dose is 150 mg three times a day. Your doctor may increase this, if necessary, up to a maximum dose of 6 g per day.

• **Mendelson’s Syndrome**  
150 mg the evening before and a further dose of 150 mg 2 hours before administration of a general anaesthetic.

**Children from 3 to 11 years of age and over 30 kg of weight**  
Children require a reduced dosage depending on how much they weigh.

• **To treat stomach or duodenal (small intestine) ulcer**  
2 - 4 mg for each kg of body weight, taken twice a day for 4 weeks. If necessary another 4 weeks of treatment can be given.  
The maximum dose is 300 mg ranitidine each day.

• **To treat reflux oesophagitis, indigestion, dyspepsia or heartburn**  
2.5 - 5 mg for each kg of body weight, taken twice a day. The maximum dose is 600 mg each day.

**Children under 3 years of age**  
Ranitidine is not recommended for use in children under 3 years of age.

**Patients with severe kidney problems**  
150 mg at bedtime for four to eight weeks. Your doctor may increase this if necessary.

**If you take more Ranitidine than you should**  
If you (or someone else) swallow a lot of the tablets all together, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately.  
Please take this leaflet, any remaining tablets, and the container with you to the hospital or doctor so that they know which tablets were consumed.

**If you forget to take Ranitidine**  
If you forget to take a tablet, take one as soon as you remember, unless it is nearly time to take the next one. DO NOT take a double dose to make up for a forgotten dose.

**If you stop taking Ranitidine**  
DO NOT stop taking your medicine without talking to your doctor first even if you feel better.

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

4. **Possible side effects**

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

**Stop taking the tablets and tell your doctor immediately** or go to the casualty department at your nearest hospital if the following happens:

• an allergic reaction; signs of this may include swelling of the lips, face or neck leading to severe difficulty in breathing or wheezing, severe skin rash or hives, fever, low blood pressure or chest pain.

This is a very serious but rare side effect. You may need urgent medical attention or hospitalisation.

**Tell your doctor immediately if you notice any of the following serious side effects:**
- severe pain in the abdomen and back, which may be a sign of inflammation of the pancreas
- yellowing of the skin or whites of the eyes, which may be a sign of inflammation of the liver

These are serious but very rare side effects. You may need urgent medical attention.

The following side effects have been reported at the approximate frequencies shown:

**Uncommon (may affect up to 1 in 100 users)**
- abdominal pain
- constipation
- feeling sick (these effects usually diminish with continued treatment.

**Rare (may affect up to 1 in 1000 users)**
- skin rash
- blood tests may show changes in results of liver function tests, or increased levels of creatinine.

**Very Rare (may affect up to 1 in 10000 users)**
- headache
- dizziness
- blurred vision
- slower or faster heart beat
- involuntary movements
- reduction in the number of white blood cells, which makes infections more likely
- reduction in blood platelets, which increases risk of bleeding or bruising
- mental confusion, depression, hallucinations (seeing or hearing things which are not real)
- inflammatory skin eruptions
- hair loss
- inflammation in the kidneys
- inflammation of the blood vessels; symptoms may include fever, swelling and a general sense of feeling ill
- joint and muscle pain
- men may experience inability to get or maintain an erection (impotence)
- men may experience swelling or discomfort of the breasts
- shortness of breath
- diarrhoea

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

You can also report side effects directly via the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

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 store the tablets above 25°C. Store the tablets in the original container.
Do not use Ranitidine after the expiry date that is stated on the outer packaging. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Ranitidine Tablets contain(s):
- The active ingredient is ranitidine (as hydrochloride) 150 or 300mg.
- The other ingredients are microcrystalline cellulose (E460), croscarmellose sodium, magnesium stearate and colloidal silicon dioxide.
- The tablet coating contains: polyethylene glycol, hypromellose (E464), polydextrose (E1200), vanillin, titanium dioxide (E171) and carnauba wax (E903).

What Ranitidine Tablets look(s) like and contents of the pack:
- Ranitidine 150 mg Tablets are white, round, biconvex, film-coated tablets engraved with ‘5C1’
- Ranitidine 300 mg Tablets are white, capsule shaped, biconvex, film-coated tablets engraved with ‘5C3’
- The tablets are available in blister packs of 28, 30, 56, 60, 84, 112 and 120 tablets and HDPE tablet containers of 100, 250, 500 and 1000 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation holder and company responsible for manufacture: TEVA UK Limited, Eastbourne, BN22 9AG

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