RANITIDINE 150 mg TABLETS
RANITIDINE 300 mg TABLETS
(ranitidine hydrochloride)

Read all of this leaflet carefully before you start taking this medicine.
- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

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2. BEFORE YOU TAKE RANITIDINE TABLETS
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1. WHAT RANITIDINE TABLETS ARE FOR
Ranitidine Tablets belongs to a group of medicines called 'H₂-antagonists'. They reduce the amount of acid in your stomach and in adults are used to treat:
- ulcers in the stomach or first part of the small intestine (duodenum)
- problems caused by acid in the food passage (reflux oesophagitis)
- Zollinger-Ellison syndrome, and ulcers caused by serious illnesses.

For children (aged 3 to 18 years), Ranitidine Tablets are used to:
- treat ulcers in the stomach or first part of the small intestine (duodenum)
- treat and prevent problems caused by acid in the food pipe (oesophagus) or too much acid in the stomach

2. BEFORE YOU TAKE RANITIDINE TABLETS
Do not take Ranitidine Tablets if you have:
- an allergy (hypersensitivity) to ranitidine or any of the other ingredients in the product (see section 4 ‘possible side effects’ and section 6 ‘what Ranitidine Tablets contain’)
- porphyria (a rare inherited metabolism disorder which causes abdominal pains)

Take special care with Ranitidine Tablets
Speak to your doctor before taking Ranitidine Tablets if you have:
- a history of stomach cancer in your family
- kidney problems

Please be aware that Ranitidine Tablets may give a false result for liver function tests.

Taking other medicines
Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
In particular, tell your doctor if you are taking any of the following as they may not work effectively if taking Ranitidine:
- ketoconazole (an antifungal agent)
- drugs used for HIV: atazanavir, delavirdine
- gefitinib (drug used in the treatment of certain types of cancer)
- drugs which induce sleep (triazolam, midazolam)
- theophylline (used in the treatment of asthma)
- lidocaine (local anesthetic)
- phenytoin (treatment of epilepsy)
- propranolol (treatment of hypertension)
- glipizide (used to treat diabetes)
- theophylline (used in the treatment of asthma)
- procainamide (for irregular heartbeat)
- blood thinning agent: warfarin

Taking Ranitidine Tablets with food and drink
Absorption is not significantly impaired by food or antacids.

Pregnancy and breast-feeding
Ask your doctor for advice before taking Ranitidine Tablets if you are pregnant, planning to become pregnant or are breast-feeding.

Always take Ranitidine Tablets exactly as your doctor has told you.
The usual doses are as follows:

Adults and adolescents (12 years and older)
Treatment of stomach or duodenal ulcers:
Take one 150 mg tablet twice a day, one in the morning and one in the evening OR one 300 mg tablet at bedtime.
For maintenance, the usual dose is 150 mg at bedtime.
Recommended duration of treatment is 4 to 8 weeks

Treatment of reflux oesophagitis:
Take one 150 mg tablet twice a day OR one 300 mg tablet at bedtime.
In severe oesophagitis, take one 150 mg tablet four times a day for a maximum of 12 weeks.

Zollinger-Ellison syndrome:
Take one 150 mg tablet three times a day. This may be increased as necessary

Patients with kidney disease
Your doctor may prescribe a lower dosage and will tell you how long to take the tablets for.
The dose is usually 150 mg at night for 4-8 weeks but will depend on the type and severity of your disease.
If healing has not occurred, take 150 mg twice daily, followed by 150 mg at night for maintenance.

Elderly
In patients with normal renal function, the dose of Ranitidine Tablets are the same as for younger adults.
Children (3 to 11 years and over 30kg of weight)
Your doctor will work out the dose depending on the child’s bodyweight.

The recommended oral dose for the treatment of peptic ulcer is 4 mg/kg/day to 8 mg/kg/day administered as two divided doses, to a maximum dose of 300 mg ranitidine per day.

The usual dose for the treatment of excess acid is 5 – 10 mg/kg/day, administered as two divided doses, for two weeks.

If you take more Ranitidine Tablets than you should
If you or someone else swallows more tablets than they should, contact a doctor or the nearest hospital emergency department immediately, taking any remaining tablets and the box if possible.

If you forget to take Ranitidine Tablets
If you miss a dose, take your dose as soon as you can, then carry on as before. Do not take an extra dose to make up for the forgotten one.

If you stop taking Ranitidine Tablets
Take Ranitidine Tablets as directed for as long as your doctor has told you. Do not stop taking them, even if you feel better, because your symptoms may return.

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 Tablets can cause side effects, although not everybody gets them.

You may suffer an allergic reaction; if any of the following side effects come on soon after taking these tablets stop the tablets and tell your doctor immediately:

- sudden wheeziness or tightness in the chest
- swelling on the eyelids, face, or lips with or without a lumpy skin rash (‘hives’) anywhere on the body
- unexplained fever
- feeling faint, especially on standing up

The following have also been reported:

Rare side effects (affects more than 1 in 10,000 people):

- liver inflammation, which might cause one or more of the following:
  - nausea (feeling sick)
  - vomiting (being sick)
  - loss of appetite
  - generally feeling unwell
  - fever
  - itching
  - yellowing of the skin and eyes
  - dark coloured urine
- unusual tiredness, shortness of breath or tendency to infections or bruising which can be caused by upsets to “blood counts”

Very rare side effects (affects less than 1 in 10,000 people):

- anaphylactic shock (severe allergic reaction)
- slow or irregular heart beat
- severe stomach pain cause by inflamed pancreas
- diarrhoea
- feeling of depression
- hallucinations
- blurred vision, reversible
- pains in muscles or joints
- uncontrolled movements, inflammation of blood vessels (vasculitis)

- hair loss (alopecia)
- breast enlargement in men
- impotence (inability to attain or sustain an erection for the performance of a sexual act)
- reversible mental confusion
- headache
- dizziness
- erythema multiforme (a red rash caused by hypersensitivity to a drug or disease or other allergen)
- blood count changes (leucopenia (abnormally low number of white blood cells in the circulating blood), thrombocytopenia (abnormally small number of platelets in the blood))

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE RANITIDINE TABLETS
Keep out of the reach and sight of children.

Store tablets in the original package and do not use after the expiry date stated on the label.

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.

If the tablets become discoloured or show signs of deterioration, you should seek the advice of your pharmacist.

6. FURTHER INFORMATION

What Ranitidine Tablets contain
Active substance is ranitidine hydrochloride equivalent to ranitidine 150 mg or 300 mg.

The other ingredients are microcrystalline cellulose (E460), hypromellose (E464), croscarmellose sodium (E468), castor oil, colloidal anhydrous silica, purified talc (E553b), magnesium stearate, ferric oxide yellow (E172) and titanium dioxide (E171).

What Ranitidine Tablets look like and contents of the pack
Ranitidine Tablets are round, film-coated, creamish yellow tablets. The 150 mg and 300 mg tablets are embossed with “MR150” or “MR300”.

The ranitidine tablets are available in blister sheets of 5, 7, 8, 10, 14, 15, 16, 20, 24, 28, 30, 32, 40, 45, 48, 50, 56, 60, 64, 72, 75, 80, 88, 90, 96, 98, 100, 105, 112, 120 and 150 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder
Activase Pharmaceuticals Limited, 11 Boumpoulina, 3rd Floor P.C. 1060, Nicosia, Cyprus

Manufacturer
Medrech PLC
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Surrey TW9 3QD, UK

For more information about this product, please contact the Marketing Authorisation Holder.

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Ranitidine 300 mg Tablets - PL No.: 28444/0103

A0102-0103/O/PIL/G2
Product: Ranitidine 150 mg & 300 mg Tablets

MA Holder: Activase
PL Number: 28444/0102 & 0103
Livery: Genesis
Manufacturer:

Artwork Code/Version: A0102-0103/O/PIL/G2
Page:
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Comments:
Arial Narrow font style, main font size is 9.3 pt

Colours:
- Black
- Non printing colours
  - Profile

Artwork Component:
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