

RANITIC[®] TABLET

Ranitidine hydrochloride (150mg)

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What Ranitic[®] is used for

Ranitic[®] contains the active ingredient Ranitidine hydrochloride.

Ranitic[®] is used in:

- Prevention and management of duodenal and stomach ulcers
- Management of Zollinger – Ellison syndrome (a rare condition where the stomach produces very large amounts of acids)
- Management of reflux oesophagitis (inflammation of oesophagus accompanied by the regurgitating of stomach acid)
- Management of people at risk of stress – related ulceration

How Ranitic[®] works

Ranitidine hydrochloride belongs to a group of medicines called H₂-receptor antagonist. Ranitidine works by reducing the amount of acid produced in the stomach, relieving the pain and allows the ulcers or reflux disease to heal.

Before you use Ranitic[®]

- When you must not use it

- Have ever had any allergic reactions or been told that you are allergic to Ranitidine hydrochloride, the active ingredients or to any of the other ingredients listed in this leaflet.

- Before you start to use it

Tell your doctor if you:

- Have allergies to any other medicines, food, preservatives or dyes
- Suffer from stomach cancer
- Have any kidney disease
- Suffer from acute porphyria (hereditary disorder that affect the nervous system)

- Are pregnant, planning to become pregnant or are breastfeeding

If you are not sure whether you should start taking this medicine, consult your doctor.

- Taking other medicines

Some medicines and Ranitic[®] may interfere with each other. It is important to tell your doctor or pharmacist if you are taking:

- Sucralfate, used to treat ulcers
- Procainamide or N-acetylprocainamide, to treat irregular heart beat
- Triazolam, to induce sleep
- Anti-anxiety medication, eg. Midazolam
- Glipizide, an anti-diabetic medicine
- Ketoconazole, an antifungal medicine
- Atazanavir and Delavirdine, used in the treatment of human immunodeficiency virus (HIV)
- Gefitinib, used to treat certain cancers

This may not be a complete list of all interactions that may occur. Ask your doctor or pharmacist if Ranitidine hydrochloride may interact with other medicines that you take.

- Pregnancy and breast-feeding

Ask your doctor for advice before taking any medicine.

Safety of Ranitidine hydrochloride is not fully established in pregnancy. Your doctor will discuss with you the risks and benefit of taking Ranitic[®] during pregnancy.

Ranitic[®] passes into mother's milk. Ask your doctor for advice if you are breastfeeding or about to start breastfeeding while taking Ranitic[®].

How to use Ranitic[®]

Always take Ranitic[®] exactly according to the instructions given to you by your doctor or pharmacist. Check with your doctor or pharmacist if you are not sure.

- How much to use

Depending on your conditions, different dosage will be given. Generally, the usual dose is 150mg twice daily or 300mg at bed

time. Patient with Zollinger-Ellison syndrome may require a higher dosage.

Children

Your doctor will advise you whether your child is suitable to use Ranitic[®]. Your child's body weight will be taken into account before deciding on the dosage by your doctor.

Your doctor will discuss with you the risks and benefit of taking Ranitic[®] in children.

- When to use it

Take your medicine as directed and the duration of treatment is to be determined by your doctor or pharmacist.

- How long to use it

Continue to take your medicine as long as your doctor tells you. The duration of treatment with Ranitic[®] depends on the condition it is being used to treat. It is important to keep taking this medicine even if you feel well.

- If you forget to use it

Take your dose as soon as you remember and continue to take it as you would normally. If it is time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

- If you use too much (overdose)

If you or anyone else takes too many tablets, you should immediately go to your nearest hospital emergency department or tell your doctor. Do this even if there are no signs of discomfort or poisoning. Take the carton or any remaining tablets you have with you.

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

While you are using it

- Things you must do

- Always take Ranitic[®] exactly according to the instructions given to you by your doctor or pharmacists. If you are unsure, check with your doctor or pharmacist.

• Inform your doctor or pharmacist if you are taking or if you have recently taken any other medicines, including medicines obtained without a prescription such as supplements or traditional medicines.

• If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Ranitic®.

- Things you must not do

• Do not give this medication to anyone else, even if they have the same condition as you.

- Things to be careful of

Taking Ranitic® may cause dizziness or light-headedness. If you have any of these symptoms, do not drive or operate any machinery.

Side effects

Like many medicines, Ranitic® may cause side effects in some people, particularly when you first taking them but not everyone will get it.

Tell your doctor or pharmacist if you notice the following side effects and it worries you:

- Tiredness
- Dizziness
- Drowsiness
- Insomnia
- Constipation
- Diarrhea
- Nausea
- Vomiting
- Abdominal discomfort & pain
- Pancreatitis (inflammation of the pancreas)
- Reversible hepatitis (inflammation of the liver), jaundice

Tell your doctor as soon as possible if you notice any of the following:

- Arthralgia (joint pain)
- Myalgia (muscle pain)
- Reversible mental confusion, agitation, depression and hallucinations (mostly in severely ill and/or elderly people)
- Reversible blurred vision
- Reversible involuntary movements, muscle twitching or spasms
- Bradycardia (slow heart beat)
- Impotence in male
- Growth of breasts in male
- Urticaria (raised, often itchy, red rashes, also called 'hives')

• Erythema multiforme (skin disorder due to an allergic reactions or infection)

• Hair loss

The above list is the rare side effects of the medicine.

The following are serious side effects. You may need urgent medical attention.

- Reversible blood disorders (e.g. low white blood cells, low red blood cells, and low platelet counts. Look out for:
 - symptoms of infections (fever, chills, sore throat, mouth ulcers)
 - symptoms of bleeding (easily bruise, gum bleeding, black tarry stool)
 - symptoms of anemia (pale skin, dizziness, weakness, shortness of breath).
- Severe allergic reactions such as:
 - difficulty breathing
 - swelling of face, lips, tongue, hands or legs
 - itching rash or hives

Tell your doctor or pharmacist if you notice anything else that makes you feel unwell.

Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting)

Storage and Disposal of Ranitic®

- Storage

Store in a cool, dry place, below 25° C. Protect from heat, light and moisture.

Keep out of the reach and sight of children.

- Disposal

Do not use Ranitic® after the expiry date which is stated on the carton or blister.

If your doctors tell you to stop taking Ranitic® or the expiry date has passed, ask your pharmacist the proper way to dispose the remaining medicines.

Product Description

- What it looks like

Ranitic® Tablet is a yellow, round, biconvex tablet with score notch on one side.

- Ingredients

- Active ingredient

Each tablet contains 150mg of Ranitidine hydrochloride.

- Inactive ingredients

Sodium starch glycollate, PEG 4000, Maize starch, Methylhydroxypropylcellulose, Lactose monohydrate, Colloidal anhydrous silica, Magnesium stearate, Calcium hydrogen phosphate dihydrate, Titanium dioxide, Yellow ferric oxide, Microcrystalline cellulose.

- Packing

It is packed in a box of (5x10 film-coated tablets) and (10x10 film-coated tablets).

- MAL Number

MAL19988460AZ

Manufacturer

Salutas Pharma GmbH
Otto-von-Guericke-Allee 1,
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For:

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Product Registration Holder

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