

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 more 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.

RANID 150 mg film-coated tablets

Ranitidine

What is in this leaflet

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

1. WHAT RANID IS AND WHAT IS IT USED FOR

Ranitidine belongs to a group of medicines called H2 receptor antagonists. These drugs reduce the amount of acid produced in your stomach. For adults (including the elderly) **RANID** are used to

- heal and stop ulcers in the stomach, or the part of the gut it empties into (the duodenum) including the ulcers caused by the drugs used in the treatment of arthritis (non-steroidal anti-inflammatory drugs - NSAIDs).
- reduce infections in your stomach, when taken with antibiotics.
- stop stomach ulcers when they are a side effect of some medicines.
- stop ulcers from bleeding.
- heal and stop problems caused by acid in the food pipe (oesophagus) or too much acid in the stomach. Both of these can cause pain or discomfort sometimes known as "indigestion", "dyspepsia" or "heartburn".
- treat Zollinger-Ellison Syndrome (a disease of the pancreas which causes excess acid production in the stomach and can cause ulceration of the stomach, duodenum, gut and gullet).
- stop acid coming up from the stomach while under anaesthetic during an operation and in women during labour.

For children (3 to 18 years) **RANID** are used to:

- heal ulcers in the stomach, of the part of the gut it empties into (the duodenum)
 - heal and stop problems caused by acid in the food pipe (oesophagus) or too much acid in the stomach. Both of these can cause pain or discomfort sometimes known as "indigestion", "dyspepsia" or "heartburn".
- If you are not sure why you are taking these tablets, ask your doctor or pharmacist.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE RANID

Do not take RANID if:

-you are allergic (hypersensitive) to ranitidine or any of the other ingredients of the **RANID** (listed in section 6).

If you are not sure, talk to your doctor or pharmacist before taking **RANID**.

Warnings and precautions

Check with your doctor or pharmacist if any of the below mention warnings apply to you, or have ever applied to you in the past.

- If you have stomach cancer.
 - If you have kidney problems. Your doctor may reduce your dose if your kidneys do not work properly.
 - If you have stomach ulcers before and you are taking Non-Steroidal Anti-inflammatory (NSAID) medicines (such as ibuprofen, naproxen).
 - If you have a rare condition called acute porphyria.
 - If you are over 65 years old.
 - If you have lung disease.
 - If you are diabetic.
 - If you have any problems with your immune system.
- If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using this medicine.

Other medicines and RANID

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because **RANID** can affect the way some other medicines work and also some other medicines can affect the way **RANID** work.

In particular tell your doctor or pharmacist if you are taking any of the following medicines:

- Non-Steroidal Anti-Inflammatory (NSAID) medicines (such as aspirin, ibuprofen, naproxen)
- for pain and inflammation.
- lidocaine, a local anaesthetic.
- propranolol, procainamide or n-acetylprocainamide for heart problem.
- diazepam, for worry or anxiety problems.

- phenytoin for epilepsy.
- theophylline for breathing problems (asthma).
- warfarin for thinning your blood.
- glipizide for lowering blood glucose.
- atazanavir or delavirdine for treating HIV infection.
- triazolam for insomnia.
- gefirtinib for lung cancer.
- ketoconazole, itraconazole - anti-fungal medicines, sometimes used for treating thrush.
- sucralfate for active duodenal ulcers.

Midazolam is a medicine that may be given to you just before you have an operation. Tell the doctor you are taking **RANID** before your operation in case he or she wants to give you midazolam.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking **RANID**.

Pregnancy, breast-feeding and fertility

If you are pregnant, thinking of becoming pregnant or are breast-feeding, you should not take this medicine unless your doctor advises it is essential. Ask your doctor or pharmacist for advice before taking any medicine, if you are pregnant or breast-feeding.

Driving and using machines

Ranitidine has no or negligible influence on the ability to drive and use machines.

RANID contain Lactose

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 is because **RANID** contains Lactose, a type of sugar.

3. HOW TO TAKE RANID

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Taking this medicine:

- To be taken orally.
- Swallow each tablet whole with a glass of water.

The usual dosage(s) are described below:

Adults (including the elderly) and adolescents (12 years and over):

- 150 mg in the morning and 150 mg in the evening, or
- 300 mg at bedtime.

Your exact dose will depend on your particular stomach condition, your doctor will tell you the dose you should take.

Children 12 years and over

Your doctor will work out the right dose for you based on the adult dosage given.

Children (from 3 to 11 years and over 30 kg weight):

Your doctor will work out the right dose for you based on your child's weight.

Treatment for stomach or duodenal (small intestine) ulcers:

The usual dose is 2 mg for each kg of body weight, twice a day for four weeks. This dose may be increased to 4 mg for each kg of body weight, twice a day. Take each dose about 12 hours apart. The duration of treatment may be increased to 8 weeks.

Treatment for oesophageal reflux (heart burn due to too much acid):

The usual dose is 2.5 mg for each kg of body weight, twice a day for two weeks. This dose may be increased to 5 mg for each kg of body weight, twice a day. Take each dose about 12 hours apart.

If you take more RANID than you should

If you or anyone else takes more than your prescribed dose, contact your nearest hospital casualty department, or tell your doctor, immediately. Take any remaining tablets and them container with you to give to the doctor.

If you forget to take RANID

If you have missed a dose, take this dose as soon as you remember. However, if it is nearly time for your next dose, skip the forgotten dose and carry on with your normal dosage schedule. Do not take double doses. You should check with your doctor or pharmacist if you are not sure.

If you stop taking RANID

Please consult your doctor before you stop taking the tablets. If you suddenly stop using this medicine, the symptoms that existed before your treatment may return.

If you have any further questions on the use of this medicine, ask your

doctor, pharmacist or nurse.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine. Stop taking **RANID** and see a doctor straight away, if you notice any of the following serious side effects, you may need urgent medical treatment:

- allergic reactions, the signs may include:
 - rash, itching or hives on the skin.
 - swelling of your face, lips, tongue or other parts of the body.
 - chest pain, shortness of breath, wheezing or having trouble breathing.
 - unexplained fever and feeling faint, especially when standing up.
 - kidney problems that may cause changes in the amount and colour of water you pass which
 - can lead to back pain, fever, pain when passing urine, blood in the urine and changes in blood
 - tests.
- severe stomach pain, this may be a sign of something called 'pancreatitis'.
- a slow or irregular heartbeat.

Check with your doctor as soon as possible 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 the blood (kidney function test).
- changes to liver function.

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

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

- there can be changes in the level of certain substances in your blood. This can lead to you

- feeling unusually tired or short of breath and being more likely to bruise or get an infection.
- feeling depressed, confused, seeing or hearing unexplained things (hallucinations).
- headache (sometimes severe)
- diarrhoea
- feeling dizzy or having blurred vision
- your joints or muscles are painful or swollen or you cannot control their movement.
- Heart problems (slow or irregular heart rhythm)
 - your small blood vessels can become swollen (known as 'vasculitis'). Signs of this can include: a rash, swollen joints or kidney problems.
- your liver can become swollen. This can lead to: nausea (feeling sick) or vomiting (being sick), loss of appetite or generally feeling unwell, itching, fever, yellowing of the skin and eyes or dark coloured urine.
- flushing or marks on your skin that look like targets.
- unexplained hair loss.
- impotence.
- breast tenderness and/or breast enlargement.
- breast discharge.

- inflammation of the pancreas(which may cause severe stomach pain)

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.

5. HOW TO STORE RANID

Do not store above 25°C. Store in the original package. Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What RANID contains

The active substance is ranitidine hydrochloride.

Each **RANID** 150 mg film-coated tablet contains 150 mg ranitidine hydrochloride.

The other ingredients are : lactose monohydrate, microcrystalline cellulose, povidone, croscarmellose sodium, sodium lauryl sulfate, purified water.

Manufacturer and marketing authorization holder

ZADA Pharmaceuticals Ltd.
Donji Bistarac without number
75 300 Lukavac
Bosnia and Herzegovina

What RANID looks like and content of the pack

30 film-coated tablets of 150 mg ranitidine in an HDPE bottle.
60 film-coated tablets of 150 mg ranitidine in an HDPE bottle.

Date and number of renewal of the marketing authorization

RANID, 30 film-coated tablets (HDPE bottle) in box:

Number: 04-07.3-2-4863/15

Date: 09.09.2015.

RANID, 60 film-coated tablets (HDPE bottle) in box:

Number: 04-07.3-2-4864/15

Date: 09.09.2015.

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