

PACKAGE LEAFLET: INFORMATION FOR THE USER

RANIBOS

150mg Film-coated tablets; 300mg Film-coated tablets

RANITIDINE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 •

What is in this leaflet?

1. What RANIBOS is and what it is used for
2. Before you take RANIBOS
3. How to take RANIBOS
4. Possible side effects
5. How to store RANIBOS
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1. WHAT RANIBOS IS AND WHAT IS IT USED FOR

RANIBOS® contains a medicine called ranitidine. This belongs to a group of medicines called H2-receptor antagonists. It lowers the amount of acid in your stomach.

For adults (including the elderly) RANIBOS is used to:

- heal and stop ulcers in the stomach, or the part of the gut it empties into (the duodenum)
- help clear up infection in your stomach, when taken with antibiotic medicines (medicines taken to treat germs)
- stop stomach ulcers when they are a side effect of some medicines
- stop ulcers from bleeding
- Improve problems caused by acid in the food pipe (esophagus) or too much acid in the stomach. Both of these can cause pain or discomfort sometimes known as 'indigestion', 'dyspepsia' or 'heartburn'
- Stop acid coming up from the stomach while under anesthetic during an operation.

For children (3 to 18 years) RANIBOS is used to:

- heal ulcers in the stomach, or the part of the gut it empties into (the duodenum)

- heal and stop problems caused by acid in the food pipe (esophagus) or too much acid in the stomach. Both of these can cause pain or discomfort sometimes known as 'indigestion', 'dyspepsia' or 'heartburn'.

2. BEFORE YOU TAKE RANIBOS

Do not take RANIBOS

- if you are allergic to ranitidine or any of the other ingredients of this medicine (listed in section 6).

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

Take special care with RANIBOS

Warnings and precautions

Check with your doctor or pharmacist before taking your medicine if:

- you have stomach cancer
- you have kidney problems. You will need to take a different amount of RANIBOS
- you have had stomach ulcers before and you are taking Non-Steroidal Anti-Inflammatory (NSAID) medicines
- you have a rare condition called acute porphyria
- you are over 65 years old
- you have lung disease
- you are diabetic
- 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.

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because RANIBOS can affect the way some other medicines work. Also some other medicines can affect the way RANIBOS works.

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

- Non-Steroidal Anti-Inflammatory (NSAID) medicines, for pain and inflammation
- lidocaine, a local anesthetic
- propranolol, procainamide or n-acetylprocainamide, for heart problems
- 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 delaviridine, for treating HIV infection
- triazolam, for insomnia
- gefitinib, for lung cancer
- ketoconazole, an anti-fungal medicine, sometimes used for treating thrush
- sucralfate, for treating stomach ulcers.

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

If you are not sure if any of the above apply to you, talk to your doctor, pharmacist or nurse before taking RANIBOS.

Taking food and drink with RANIBOS film-coated tablets

RANIBOS® can be administered during or between meals, because their action is not affected by the presence of food in the stomach.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist or nurse for advice before taking this medicine. You should not take this medicine unless your doctor advises it is essential.

Driving and using machines

RANIBOS should not affect your ability to drive and use machines.

Other warnings

None of the excipients does not alter the efficacy and safety of the medicine.

3. HOW TO TAKE RANIBOS

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Take this medicine by mouth.
- Swallow each tablet whole with a glass of water.

The usual dose for an adult (including the elderly) is either:

- 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.

Use in children 12 years and over:

The adult dose is given.

Use in children over 30 kg of weight and from 3 to 11 years:

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

Treatment of 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, twice a day. Take each dose about 12 hours apart. The duration of treatment may be increased to 8 weeks.

Treatment of heartburn 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, twice a day. Take each dose about 12 hours apart.

If you take more RANIBOS than you should

RANIBOS is not normally harmful if you take more than you should, unless you take many tablets at once. If this applies to you (or someone else taking this medicine), **you should go to your nearest hospital casualty department straight away.** Take the medicine pack or any remaining medicine with you so that the doctor knows what you have taken.

If you forget to take RANIBOS

If you miss a dose, take the next dose at the usual time and continue to take the medicine as instructed by a doctor.

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

If you stop taking RANIBOS

After a few days of taking the tablets you should start to feel much better. Do not stop taking the tablets without talking to your doctor or pharmacist first, otherwise the original pain and discomfort may come back.

Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

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

Stop taking RANIBOS 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, 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’
- slow or irregular heartbeat

Check with your doctor **at your next visit** if you notice any of the following:

Uncommon (may affect up to 1 in 100 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)
- feeling dizzy or having blurred vision
- your joints or muscles are painful or swollen or you cannot control their movement
- 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 colored urine
- flushing or marks on your skin that look like targets
- unexplained hair loss
- diarrhea
- impotence
- breast tenderness and/or breast enlargement
- breast discharge
- awareness of the heart beat and/or increased heart rate

Not known (frequency cannot be estimated from the available data)

- shortness of breath

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

5. HOW TO STORE RANIBOS

Keep out of the reach and sight of children.

Do not store above 30 °C.

Shelf life: 3 years.

Do not use **RANIBOS** after the expiry date which is stated on the label, 3 years from the date of manufacture.

6. FURTHER INFORMATION

What RANIBOS contains

RANIBOS® 150 mg tablet contains: 150 mg of ranitidine (as the hydrochloride).

RANIBOS® 300 mg tablet contains: 300 mg of ranitidine (as the hydrochloride).

RANIBOS® 150 mg and 300 mg film-coated tablet contains the following excipients: microcrystalline cellulose, croscarmellose sodium, colloidal silicon dioxide, magnesium stearate, color Opadry II white. Color Opadry II white contains: polyvinyl alcohol, partially hydrolyzed, titanium dioxide (E171), talc, polyethylene glycol 3350, lecithin (soya) (E322).

What RANIBOS looks like and contents of the pack

RANIBOS® 150 mg film-coated tablets are white to off-white, round-shaped, biconvex.

RANIBOS® 150 mg film-coated tablets are packed in boxes containing 20 film-coated tablets.

RANIBOS® 300 mg film-coated tablets are white to off-white, round-shaped, biconvex.

RANIBOS® 300 mg film-coated tablets are packed in boxes containing 10 film-coated tablets.

Regime of dispensing

The medicine is issued on prescription.

Manufacturer

Bosnalijek d.d. Jukićeva 53, Sarajevo, Bosniaand Herzegovina

