

PACKAGE LEAFLET: INFORMATION FOR THE USER

RANIBOS

75 mg 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
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1. WHAT RANIBOS IS AND WHAT IS IT USED FOR

RANIBOS 75 mg tablets belong to the group of drugs known as H₂ receptor antagonists. H₂-receptor antagonists act by preventing your stomach from producing too much acid.

The stomach produces acid which helps to digest food, but sometimes your stomach produces too much acid which can cause symptoms such as indigestion and heartburn. RANIBOS 75 mg film-coated tablets reduce excessive acidity in your stomach, and therefore they are used to prevent and reduce the symptoms of heartburn, increased acidity in the stomach and indigestion.

RANIBOS 75 mg film-coated tablet has the effect after 30 minutes and effectively reduces the secretion of stomach acid for 12 hours, and ensures fast and long lasting relief of these symptoms.

2. BEFORE YOU TAKE RANIBOS

Do not take RANIBOS

- if you are allergic (hypersensitive) to Ranitidine, or any of the other ingredients of this medicine

Take special care with RANIBOS, so you must tell the doctor

- if you have stomach cancer;
- if you have severe renal and / or liver disorder;
- if you are under regular medical control for any other reason;
- if you have a rare hereditary disease called porphyria;
- if you are middle-aged or older, and the symptoms of indigestion have appeared recently or you have recently noticed changes regarding these symptoms;
- if due to poor digestion you are unintentionally losing weight.

Taking other medicines

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

Talk to your doctor or pharmacist before taking RANIBOS 75 if you are taking any other medicines, including those obtained without a prescription; **particularly medicines to prevent blood clotting**, such as **warfarin**, and **non-steroidal anti-inflammatory painkillers** (e.g. **aspirin** or **ibuprofen**). This advice is even more important if you are **elderly**.

Taking food and drink with RANIBOS75 mg film-coated tablets

RANIBOS75 mg film-coated tablets 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.

Ranitidine crosses the placenta. Just like the other medicines you buy without a prescription, RANIBOS75 mg tablets should not be taken during pregnancy without consulting doctor or pharmacist first.

Ranitidine is excreted into breast milk, and nursing mothers are advised that before taking RANIBOS75 mg film-coated tablets talk to their doctor.

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.

Adults and children aged 16 years and over:

Swallow 1 tablet, with a drink of water, as soon as you have symptoms. If symptoms persist for more than one hour or return, take another tablet. Do not take more than 2 tablets in 24 hours.

To prevent your symptoms, you can take 1 tablet half an hour to an hour before eating or drinking.

Do not take the tablets for more than 6 days without the advice of your doctor or pharmacist.

Children:

RANIBOS75 mg film-coated tablets are not recommended for use in children under 16 years.

If you take more RANIBOS than you should

Follow the recommended dosage for your medication. RANIBOS75 mg film-coated tablets work in a very specific way, and in case you take more than the recommended dose, no particular difficulties are expected. Contact your doctor if you take more film-coated tablets than recommended.

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

If you suddenly stop taking this medicine, no negative effects are expected.

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.

RANIBOS 75 mg tablets are generally well tolerated, and side effects are usually mild and transient.

According to the frequency, side effects are divided into: Very common (more than 1 in 10 patients), common (less than 1 in 10 patients), uncommon (less than 1 in 100 patients), rare (less than 1 in 1000 patients), and very rare (less than 1 in 10,000 patients).

Stop taking the medicine and **tell your doctor immediately** if you experience:

- Swelling of the hands, feet, face, lips, throat and difficulty breathing and swallowing (anaphylactic shock). These side effects are very rare.
- Hives, swelling of the lips, tongue and throat, fever, shortness of breath, dizziness and chest pain (hypersensitivity reaction). These side effects are rare.

Other side effects:

Rare

- Transient changes in liver function.
- Skin rash.

Very rare

- Changes to the number of blood cells (leukopenia, thrombocytopenia). They are usually transient.
- Transient mental confusion, depression and hallucinations.
- Headache (sometimes severe), dizziness and transient involuntary movement disorders.
- Transient blurred vision.
- Slow heart rate, as well as in the implementation of other H₂-receptor antagonists.
- Vasculitis (inflammation of blood vessels).
- Acute pancreatitis. Diarrhea.
- Hepatitis with or without jaundice, usually transient.
- Erythema multiforme, alopecia (baldness).
- Musculoskeletal symptoms such as arthralgia and myalgia (pain in the joints and muscles).
- Acute interstitial nephritis (inflammation of the kidneys).
- Transient impotence. Changes in breasts in men.

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: 2 years.

Do not use **RANIBOS** after the expiry date which is stated on the label, 2 years from the date of manufacture.

6. FURTHER INFORMATION

What RANIBOS contains

One RANIBOS75 mg tablet contains: 75 mg of ranitidine (in the form of ranitidine hydrochloride).

RANIBOS75 mg film-coated tablet contains the following excipients: microcrystalline cellulose, croscarmellose sodium, colloidal silicon dioxide, magnesium stearate, Opadry II, Pink.

What RANIBOS looks like and contents of the pack

RANIBOS75 mg tablets are light pink, triangular biconvex shape.

RANIBOS75 mg tablets are packed in a brown glass bottle with 30 film-coated tablets and silica gel, in a box.

Regime of dispensing

The medicine is issued without doctor's prescription.

Manufacturer

Bosnalijek d.d. Jukićeva 53, Sarajevo, Bosnia and Herzegovina