

## PACKAGE LEAFLET: INFORMATION FOR THE USER

Lansoprazol Baldacci 30 mg gastro-resistant capsules  
Lansoprazol

Read all of this leaflet carefully before you start taking this medicine as it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you are not sure, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. You should not give it to others. The medicine can be harmful to them even if they show the same signs of illness.
- If you experience any side effects, including possible side effects not listed in this leaflet, talk to your doctor or pharmacist. See section 4.

In this leaflet:

1. What Lansoprazole Baldacci is and what it is used for
2. Or what do you need to know before taking Lansoprazole Baldacci
3. How to take Lansoprazole Baldacci
4. Possible undesirable effects
5. How to store Lansoprazole Baldacci
6. Package contents and other information

### 1. WHAT LANSOPRAZOLE BALDACCI IS AND WHAT IT IS USED FOR

The active substance in Lansoprazole Baldacci is lansoprazole, which is a proton pump inhibitor. Proton pump inhibitors reduce the amount of acid the stomach produces.

Your doctor may prescribe Lansoprazole Baldacci for the following indications in adults:

- Treatment of gastric and duodenal ulcer
- Treatment of inflammation of the esophagus (reflux esophagitis)
- Prevention of reflux esophagitis
- Treatment of heartburn and acid regurgitation
- Treatment of infections caused by the bacterium *Helicobacter pylori* when given in combination with antibiotic therapy
- Treatment or prevention of gastric or duodenal ulcer in patients on continued treatment with NSAIDs [non-steroidal anti-inflammatory drugs] (NSAID treatment is used against pain or inflammation)
- Treatment of Zollinger-Ellison syndrome.

Your doctor may prescribe Lansoprazole Baldacci for another indication or at a different dose than the dose given in this package leaflet. Always follow your doctor's instructions on how to take the medicine.

If you don't feel better or if it gets worse after 14 days, you need to see a doctor.

### 2. WHAT YOU NEED TO KNOW BEFORE TAKING LANSOPRAZOLE BALDACCI

Do not take Lansoprazole Baldacci:

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

## Warnings and precautions

Tell your doctor if you have severe liver disease. The doctor may need to adjust your dosage.

Your doctor may perform or have performed an additional test called an endoscopy to diagnose your condition and/or rule out a malignancy.

If diarrhoea occurs during treatment with Lansoprazole Baldacci, contact your doctor immediately, as Lansoprazole Baldacci has been associated with a small increase in infectious diarrhoea.

When taking Lansoprazole, inflammation in the kidney may occur. Signs and symptoms may include decreased urine volume or blood in the urine and/or hypersensitivity reactions such as fever, rash, and joint stiffness. You should report these signs to your doctor.

If your doctor has given you Lansoprazole Baldacci together with other medicines to treat *Helicobacter pylori* infection (antibiotics) or with anti-inflammatory medicines to treat pain or a rheumatic condition, also read the package leaflets for these medicines carefully.

Taking a proton pump inhibitor such as Lansoprazole Baldacci, especially for a period of time longer than a year, may slightly increase the risk of fracture of the hip, wrist or spine. Talk to your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase your risk of osteoporosis).

If you have been taking Lansoprazole Baldacci for a long time (for more than 1 year) your doctor will probably keep you under regular surveillance. You should report any new or unusual symptoms and circumstances when you go to your doctor.

Talk to your doctor before taking lansoprazole:

- if you have low vitamin B12 levels or risk factors for low vitamin B12 levels and if you are on long-term treatment with lansoprazole. Like all agents that decrease acid production, lansoprazole may reduce the absorption of vitamin B12
- whether a specific blood test (Chromogranin A) is planned
- if you have ever had skin reactions after treatment with a medicine similar to lansoprazole that reduces stomach acidity.

If you experience a rash, especially on areas of skin exposed to the sun, talk to your doctor as soon as possible, as you may need to stop your treatment with lansoprazole. Remember to also mention any other adverse effects, such as joint pain.

## Other medicines and Lansoprazole Baldacci

Talk to your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

In particular, tell your doctor or pharmacist if you are taking medicines containing any of the following active substances, as Lansoprazole Baldacci may affect the way these medicines work:

- HIV protease inhibitors such as atazanavir and nelfinavir (used to treat HIV)
- methotrexate (used to treat autoimmune diseases and cancer)
- ketoconazole, itraconazole, rifampicin (used to treat infections)
- digoxin (used to treat heart problems)
- warfarin (used to treat blood clots)

- theophylline (used to treat asthma)
- tacrolimus (used to prevent transplant rejection)
- fluvoxamine (used to treat depression and other psychiatric illnesses)
- antacids (used to treat heartburn or acid regurgitation)
- sucralfate (used to treat ulcers)
- St. John's wort (*Hypericum perforatum*) (used to treat mild depression).

#### Lansoprazole Baldacci with Food and Beverage

To get the best result from the drug, you should take Lansoprazole Baldacci at least 30 minutes before meals.

#### Pregnancy and breastfeeding

If you are pregnant or breast-feeding, think you may be pregnant or plan to become pregnant, ask your doctor or pharmacist for advice before taking this medicine.

#### Driving and using machines

In patients taking Lansoprazole Baldacci, undesirable effects such as dizziness, lightheadedness, fatigue and visual disturbances sometimes occur. If you have effects like these, you should be careful, because your ability to react may be diminished.

You are responsible for deciding whether you are able to drive motor vehicles or perform other tasks that require increased concentration. The use of medications, due to their effects or undesirable effects, is one of the factors that can reduce your ability to perform these tasks safely. In other sections you can find descriptions of these effects.

Read all the information in this package leaflet.

Consult your doctor or pharmacist if you have any questions.

Lansoprazole Baldacci contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

### 3. HOW TO TAKE LANSOPRAZOLE BALDACCI

Take this medication exactly as directed by your doctor. Check with your doctor or pharmacist if you are not sure.

Take the entire capsule with a glass of water. If you find the capsules difficult to take, your doctor may advise you on alternative ways to take the medicine. Do not crush or chew the capsules or their contents, as this will prevent them from working properly.

If you take Lansoprazole Baldacci once a day, try to take it at the same time each day. You may get better results if you take Lansoprazole Baldacci first thing in the morning on an empty stomach.

If you take Lansoprazole Baldacci twice a day, you should take the first dose in the morning and the second in the evening.

The dose of Lansoprazole Baldacci depends on your situation. Below are the usual doses of Lansoprazole Baldacci for adults. Sometimes your doctor may prescribe you a different dose and tell you how long the treatment lasts.

Treatment of heartburn and acid regurgitation: one capsule of 15 or 30 mg every day for 4 weeks. If symptoms persist, tell your doctor. If symptoms do not resolve within 4 weeks, contact your doctor.

Treatment of duodenal ulcer: one 30 mg capsule every day for 2 weeks.

Treatment of gastric ulcer: one 30 mg capsule every day for 4 weeks.

Treatment of inflammation in the oesophagus (reflux oesophagitis): one 30 mg capsule every day for 4 weeks.

Long-term prevention of reflux esophagitis: one 15 mg capsule every day, your doctor may adjust the dose to one 30 mg capsule every day.

Treatment of *Helicobacter pylori* infection: The usual dose is one 30 mg capsule in combination with two different antibiotics in the morning and one 30 mg capsule in combination with two different antibiotics in the evening. Usually, the treatment is done every day for 7 days.

The recommended combinations of antibiotics are:

30 mg Lansoprazole Baldacci with 250-500 mg clarithromycin and 1000 mg amoxicillin

30 mg Lansoprazole Baldacci with 250 mg clarithromycin and 400-500 mg metronidazole

If you are being treated for an infection because you have an ulcer, it is unlikely that your ulcer will come back if the infection is successfully treated. For the medicine to work optimally, take it at the right time and do not miss a dose.

Treatment of gastric or duodenal ulcer in patients on continuous treatment with NSAIDs: one 30 mg capsule every day for 4 weeks.

Prevention of gastric or duodenal ulcer disease in patients on continued treatment with NSAIDs: one 15 mg capsule every day, your doctor may adjust the dose to one 30 mg capsule every day.

Zollinger-Ellison syndrome: The recommended starting dose is two 30 mg capsules every other day, thereafter, depending on your response to Lansoprazole Baldacci, your doctor will decide the most appropriate dose for you.

Use in children

Lansoprazole Baldacci should not be given to children.

If you take more Lansoprazole Baldacci than you should

If you take more Lansoprazole Baldacci than you should, seek medical advice quickly.

If you forget to take Lansoprazole Baldacci

If you forget to take a dose, take it as soon as you remember, unless it is close to the time for your next dose. If this happens, skip the missed dose and take the remaining capsules as normal. Do not take a double dose to make up for a forgotten capsule.

## Stopping Lansoprazole Baldacci

Don't stop treatment early just because your symptoms have improved. Your condition may not have been completely treated and may reappear if you do not complete treatment.

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

### 4. POSSIBLE UNDESIRABLE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

#### Common undesirable effects

These can affect up to 1 in 10 people

- headache, dizziness
- diarrhoea, constipation, stomach pain, malaise, flatulence, dry or sore mouth or throat
- rash, itching
- changes in liver function test values
- fatigue
- benign polyps in the stomach.

#### Uncommon undesirable effects

These can affect up to 1 in 100 people

- depression
- joint or muscle pain
- fluid retention or bloating
- Changes in blood cell counts.

#### Rare undesirable effects

These can affect up to 1 in 1000 people

- fever
- restlessness, drowsiness, confusion, hallucinations, insomnia, visual disturbances, vertigo
- change in taste, loss of appetite, inflamed tongue (glossitis)
- skin reactions such as burning or stinging sensations, bruising, redness and excessive sweating
- sensitivity to light
- Hair loss
- tingling sensation on the skin (paresthesia), tremor
- anemia (pallor)
- kidney problems
- pancreatitis
- inflammation of the liver (a yellow tinge may appear on the skin and eyes)
- swelling of the chest in men, impotence
- candidiasis (fungal infection, may affect the skin or mucous membrane)
- angioedema; You should see your doctor immediately if you experience symptoms of angioedema, such as swelling of the face, tongue or pharynx, difficulty swallowing, hives and difficulty breathing.

#### Very rare undesirable effects

These can affect up to 1 in 10,000 people

- severe hypersensitivity reactions, including shock. Symptoms of a hypersensitivity reaction may include fever, rash, swelling, and sometimes a drop in blood pressure
- inflammation of the mouth (stomatitis)
- colitis (inflammation of the intestine)
- changes in test values such as sodium, cholesterol and triglyceride levels
- very severe skin reactions with redness, blistering, severe inflammation and skin loss
- very rarely: Lansoprazole Baldacci may cause a reduction in the number of white blood cells and their resistance to infections may be decreased. If you have an infection with symptoms such as fever and severe deterioration of your general condition, or fever with local symptoms of infection such as sore throat/pharynx/mouth or urinary problems, you should see your doctor immediately. A blood test will be done to assess a possible reduction in white blood cells (agranulocytosis).

#### Frequency not known

- If you have been taking Lansoprazole Baldacci for more than three months, it is possible that your blood levels of magnesium have dropped. Low magnesium levels can manifest in fatigue, involuntary muscle contractions, disorientation, seizures, dizziness, or increased heart rate. If you experience any of these symptoms, talk to your doctor immediately. Low magnesium levels can also lead to reductions in potassium or calcium levels in the blood. Your doctor may decide to do regular blood tests to monitor your magnesium levels.
- Skin rashes, possibly accompanied by joint pain.
- Visual hallucinations.

#### Reporting of undesirable effects

If you experience any side effects, including possible side effects not listed in this leaflet, talk to your doctor or pharmacist. You can also report undesirable effects directly to INFARMED I.P. through the contacts below. By reporting side effects, you are helping to provide more information about the safety of this medicine.

Site internet: <http://www.infarmed.pt/web/infarmed/submissaoram>  
(preferably)

or through the following contacts:

Direção de Gestão do Risco de Medicamentos  
Parque da Saúde de Lisboa, Av. Brasil 53  
1749-004 Lisboa  
Tel: +351 21 798 73 73  
Linha do Medicamento: 800222444 (gratuita)

## 5. HOW TO STORE LANSOPRAZOLE BALDACCI

Do not store above 30°C.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister pack and carton. The expiry date corresponds to the last day of the month indicated.

Do not dispose of any medicines in the sewer or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

## 6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Lansoprazole Baldacci contains

- The active substance is lansoprazole
- The other ingredients are: Sucrose and Corn Starch Microgranules, Meglumine, Mannitol, Hypromellose, Macrogol 6000, Talc, Polysorbate 80, Titanium Dioxide (E171), Methacrylic Acid and Ethyl Acrylate Copolymer, Quinoline Yellow (E104), Gelatin and Sodium Lauryl Sulfate.

What Lansoprazole Baldacci looks like and contents of the pack

Lansoprazole Baldacci capsules are white and contain white enteric-coating granules.

Not all pack sizes may be marketed.

Marketing Authorization Holder and Manufacturer

Marketing Authorization Holder

BALDACCI PORTUGAL, S.A.  
Rua Cândido de Figueiredo, 84 – B  
1549-005 Lisboa  
Tel.: 217783031  
Fax: 217785457  
E-mail: [medico@baldacci.pt](mailto:medico@baldacci.pt)

Manufacturer

Laboratorios Liconsa, S.A.  
Avda. Miralcampo, nº 7  
Polygon Industrial Miralcampo  
19200 Azuqueca de Henares  
Guadalajara  
Spain

This leaflet was last revised in June 2024