

## PACKAGE LEAFLET: INFORMATION FOR THE USER

### ULCERBREX 10 mg and 20 mg gastro-resistant tablets Rabeprazole sodium

**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. See section 4.

#### **What is in this leaflet:**

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

#### **1. What Ulcerbrex is and what it is used for**

Ulcerbrex tablet contains the active ingredient rabeprazole sodium. This belongs to a group of medicines called 'Proton Pump Inhibitors' (PPIs). They work by lowering the amount of acid that your stomach produces.

Ulcerbrex tablets are used to treat the following conditions:

- 'Gastro-oesophageal reflux disease' (GORD), which can include heartburn. GORD is caused when acid and food from your stomach escapes into your food pipe (oesophagus)
- Ulcers in your stomach or the upper part of your gut (intestine). If these ulcers are infected with bacteria called 'Helicobacter pylori' (H. Pylori), you will also be given antibiotics. Using Ulcerbrex tablets and antibiotics together gets rid of the infection and makes the ulcer heal. It also stops the infection and ulcer from coming back
- Zollinger-Ellison Syndrome where your stomach produces too much acid.

#### **2. What you need to know before you take Ulcerbrex**

##### **Do not take Ulcerbrex if:**

- You are allergic (hypersensitive) to rabeprazole sodium, or any of the other ingredients of Ulcerbrex (listed in Section 6 below)
- You are pregnant or think that you are pregnant
- You are breast-feeding.

Do not use Ulcerbrex if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before using Ulcerbrex.

Also see Pregnancy, breast-feeding and fertility section.

#### **Warnings and precautions**

Check with your doctor or pharmacist before taking Ulcerbrex if:

- You are allergic to other proton pump inhibitor medicines or 'substituted benzimidazoles'
- Blood and liver problems have been seen in some patients but often get better when Ulcerbrex is stopped

- You have a stomach tumour
  - You have ever had liver problems.
  - You are taking atazanavir- for HIV infection
- If you have reduced body stores or risk factors for reduced vitamin B12 and receive long term treatment with rabeprazole sodium. As with all acid reducing agents, rabeprazole sodium may lead to a reduced absorption of vitamin B12.
    - If you have ever had a skin reaction after treatment with a medicine similar to Ulcerbrex that reduces stomach acid.

If you get a rash on your skin, especially in areas exposed to the sun tell your doctor as soon as you can, as you may need to stop your treatment with Ulcerbrex. Remember to also mention any other ill-effects like pain in your joints.

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

### **Children**

Ulcerbrex should not be used in children.

If you experience severe (watery or bloody) diarrhoea with symptoms such as fever, abdominal pain or tenderness, stop taking Ulcerbrex and see a doctor straight away.

Taking a proton pump inhibitor like Ulcerbrex, especially over a period of more than one year, may slightly increase your risk of fracture in the hip, wrist or spine. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).

### **Other medicines and Ulcerbrex**

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

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

- Ketoconazole or itraconazole – used to treat infections caused by a fungus. Ulcerbrex may lower the amount of this type of medicine in your blood. Your doctor may need to adjust your dose.
- Atazanavir– used to treat HIV-infection. Ulcerbrex may lower the amount of this type of medicine in your blood and they should not be used together.
- Methotrexate (a chemotherapy medicine used in high doses to treat cancer) – if you are taking a high dose of methotrexate, your doctor may temporarily stop your Ulcerbrex treatment.

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

### **Pregnancy, breast-feeding and fertility**

- Do not use Ulcerbrex if you are pregnant or think you may be pregnant
- Do not use Ulcerbrex if you are breast-feeding or planning to breast-feed

Ask your doctor or pharmacist for advice before taking any medicine during pregnancy or while breast-feeding.

### **Driving and using machines**

You may feel sleepy while taking Ulcerbrex. If this happens, do not drive or use any tools or machines.

### **3. How to take Ulcerbrex**

Always take Ulcerbrex exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

#### **Taking this medicine**

- Only remove a tablet from the blister strip when it is time to take your medicine
- Swallow your tablets whole with a drink of water. Do not chew or crush the tablets
- Your doctor will tell you how many tablets to take and how long to take them for. This will depend on your condition
- If you are taking this medicine for a long time, your doctor will want to monitor you.

#### **Adults and older people**

##### **For 'gastro-oesophageal reflux disease' (GORD)**

##### **Treatment of moderate to severe symptoms (symptomatic GORD)**

- The usual dose is one Ulcerbrex 10 mg tablet once a day for up to 4 weeks
- Take the tablet in the morning before eating
- If your condition returns after 4 weeks treatment, your doctor may tell you to take one Ulcerbrex 10 mg tablet as and when you require it.

##### **Treatment of more severe symptoms (erosive or ulcerative GORD)**

- The usual dose is one Ulcerbrex 20 mg tablet once a day for 4 to 8 weeks.
- Take the tablet in the morning before eating.

##### **Long-term treatment of symptoms (GORD maintenance)**

- The usual dose is one Ulcerbrex 10 mg or 20 mg tablet once a day for as long as your doctor has told you.
- Take the tablet in the morning before eating.
- Your doctor will want to see you at regular intervals to check your symptoms and dosage.

##### **For ulcers of the stomach (peptic ulcers)**

- The usual dose is one Ulcerbrex 20 mg tablet once a day for 6 weeks.
- Take the tablet in the morning before eating.
- Your doctor may tell you to take Ulcerbrex for another 6 weeks if your condition does not improve.

##### **For ulcers of the intestine (duodenal ulcers)**

- The usual dose is one Ulcerbrex 20 mg tablet once a day for 4 weeks.
- Take the tablet in the morning before eating.
- Your doctor may tell you to take Ulcerbrex for another 4 weeks if your condition does not improve.

##### **For ulcers caused by H. Pylori infection and to stop them coming back**

- The usual dose is one Ulcerbrex 20 mg tablet twice a day for seven days.
- Your doctor will also tell you to take antibiotics called amoxicillin and clarithromycin.

For further information on the other medicines used for the H. Pylori treatment, see the individual product information leaflets.

##### **Zollinger-Ellison Syndrome where excess acid is produced in the stomach**

- The usual dose is three Ulcerbrex 20 mg tablets once a day to start with.
  - The dose may then be adjusted by your doctor depending on how you respond to the treatment.
- If you are on long-term treatment you will need to see your doctor at regular intervals for review of your tablets and symptoms.

**Patients with liver problems.** You should consult your doctor who will take special care when

beginning treatment with Ulcerbrex and while you continue to be treated with Ulcerbrex.

#### **If you take more Ulcerbrex than you should**

If you take more Ulcerbrex than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you.

#### **If you forget to take Ulcerbrex**

- If you forget to take a dose, take it as soon as you remember it. However, if it is almost time for your next dose, skip the missed dose and continue as usual.
- If you forget to take your medicine for more than 5 days, talk to your doctor before taking any more medicine.
- Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

#### **If you stop taking Ulcerbrex**

Relief of symptoms will normally occur before the ulcer has completely healed. **It is important that you do not stop taking the tablets until told to do so by your doctor.**

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

#### **4. Possible side effects**

Like all medicines, Ulcerbrex can cause side effects, although not everybody gets them. The side effects are usually mild and improve without you having to stop taking this medicine.

#### **Stop taking Ulcerbrex and see a doctor straight away if you notice any of the following side effects - you may need urgent medical treatment:**

- Allergic reactions – the signs may include: sudden swelling of your face, difficulty breathing or low blood pressure which may cause fainting or collapse
- Frequent infections, such as a sore throat or high temperature (fever), or ulcers in your mouth or throat
- Bruising or bleeding easily.

These side effects are rare (affect less than 1 in 1,000 people).

- Severe skin blistering, or soreness or ulcers in your mouth and throat. These side effects are very rare (affect less than 1 in 10, 000 people).

#### **Other possible side effects:**

##### **Common (affect less than 1 in 10 people)**

- Infections
- Difficulty sleeping
- Headache or feeling dizzy
- Cough, runny nose or sore throat (pharyngitis)
- Effects on your stomach or gut such as stomach pain, diarrhoea, wind (flatulence), feeling sick (nausea), being sick (vomiting) or constipation
- Aches or back pain
- Weakness or flu-like symptoms.

##### **Uncommon (affect less than 1 in 100 people)**

- Feeling nervous or drowsy
- Chest infection (bronchitis)
- Painful and blocked sinuses (sinusitis)
- Dry mouth
- Indigestion or belching

- Skin rash or redness
- Muscle, leg or joint pain
- Fractures of the hip, wrist and spine
- Bladder infection (urinary tract infection)
- Chest pain
- Chills or fever
- Changes in how your liver is working (shown in blood tests)

**Rare (affect less than 1 in 1,000 people)**

- Loss of appetite (Anorexia)
- Depression
- Hypersensitivity (includes allergic reactions)
- Visual disturbance
- Sore mouth (stomatitis) or taste disturbance
- Upset stomach or stomach pain
- Liver problems including yellowing of your skin and whites of your eyes (jaundice)
- Itchy rash or blistering skin
- Sweating
- Kidney problems
- Weight gain
- Changes in white blood cells (shown in blood tests) which may result in frequent infection.
- Reduction in blood platelets resulting in bleeding or bruising more easily than normal.

**Other possible side effects (unknown frequency)**

- breast swelling in men
- fluid retention
- Low blood levels of sodium which can cause tiredness and confusion, muscle twitching, fits and coma.
- Patients who have previously had liver problems may very rarely get encephalopathy (a brain disease).
- Rash, possibly with pain in the joints

If you are on Ulcerbrex for more than three months it is possible that the levels of magnesium in your blood may fall. Low levels of magnesium can be seen as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness, increased heart rate. If you get any of these symptoms, please tell your doctor promptly. Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium.

Do not be concerned by this list of side effects. You may not get any of them.

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Ulcerbrex**

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

Do not store this medicine above 25°C. Store in the original container.

Do not refrigerate.

Do not use Ulcerbrex after the expiry date stated on the container after “EXP”. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of packages and medicines that are no longer needed. These measures will help to protect the environment.

## **6. Contents of the pack and other information**

### **What Ulcerbrex contains**

Each Ulcerbrex 10 mg tablet contains 10 mg of the active substance rabeprazole sodium.

The other ingredients are:

Tablet core: Mannitol, magnesium oxide (E-530), hydroxypropyl cellulose (E-463), magnesium stearate (E-470B).

Intermediate coating: ethyl cellulose, magnesium oxide (E-530).

Enteric coating: hypromellose phthalate, dibutyl sebacate, talc, titanium dioxide (E-171), red iron oxide (E-172)

Each Ulcerbrex 20 mg tablet contains 20 mg of the active substance rabeprazole sodium.

Tablet core: Mannitol, magnesium oxide (E-530), hydroxypropyl cellulose (E-463), magnesium stearate (E-470B).

Intermediate coating: ethyl cellulose, magnesium oxide (E-530).

Enteric coating: hypromellose phthalate, dibutyl sebacate, talc, titanium dioxide (E-171), yellow iron oxide (E-172)

### **What Ulcerbrex looks like and contents of the pack**

**Ulcerbrex 10 mg** is supplied as round pink gastro-resistant tablets. Each pack contains 28 tablets (in 7-tablets blister packs).

**Ulcerbrex 20 mg** is supplied as round yellow gastro-resistant tablets. Each pack contains 14 or 28 tablets (in 7-tablets blister packs).

### **Manufacturer:**

#### **Dosage Form, Packaging & Labeling**

LABORATORIOS CINFA, S.A.  
Avda. Roncesvalles s/n, 31699  
Olloki (Navarra), Spain

#### **Batch Releaser**

LABORATORIOS CINFA, S.A.  
Olaz-Chipi, 10 – Polígono Industrial Areta  
31620 Huarte-Pamplona (Navarra), Spain

#### **Marketing Authorisation Holder**

LABORATORIOS CINFA, S.A.  
Olaz-Chipi, 10 – Polígono Industrial Areta  
31620 Huarte-Pamplona (Navarra), Spain

**This leaflet was last revised in Nov. 2015.**

**This is a Medicament**

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

**Council of Arab Health Ministers  
Union of Arab Pharmacists**