

## PATIENT INFORMATION LEAFLET

### **Erbinna 40 mg I.V.vial containing lyophilised powder for injection**

#### **Use by intravenous route**

- **Active substance :** Omeprazole sodium (equivalent to 40 mg omeprazole)
- **Excipients :** Sodium hydroxide, citric acid, polyethylene glycol 400 and water for injection

**Read all of this leaflet carefully before you start using 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.*

*Tell your doctor if you go to a doctor or a hospital when you are using this medicine.*

*Follow these instructions exactly. Do not use **high or low** doses other than the recommended dose for the drug.*

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

1. **What ERBINNA is and what it is used for**
2. **What you need to know before you use ERBINNA**
3. **How to use ERBINNA?**
4. **Possible side effects**
5. **How to store ERBINNA?**

#### **1. What ERBINNA is and what it is used for?**

ERBINNA belongs to a group of medicines called ‘proton pump inhibitors. They work by reducing the amount of acid that your stomach produces.

ERBINNA consists of a little glass vial and solvent containing ampoule. Each little vial contains 40 mg omeprazole equivalent to 42.6 mg omeprazole sodium. Each ampoule contains solvent for reconstitution.

Your drug is used to treat the following conditions:

- Inflammation of the esophagus due to acid escaping from the stomach to the esophagus; pain (in reflux disease and esophageal reflux disease),
- Ulcer in the upper intestine (duodenal ulcer), ulcer in the esophagus (peptic ulcer) ulcer) or gastric ulcer (gastric ulcer),
- Non-steroidal anti-inflammatory (hormone-free anti-inflammatory) caused by drugs ulcers of the stomach and ulcers in the upper part of the intestines,

- In cases of excessive acidity in the stomach, called Zollinger-Ellison syndrome.

## 2. What you need to know before you use ERBINNA

### Do not use ERBINNA

- If you are allergic to omeprazole or any of the other ingredients of ERBINNA, If you are allergic to other proton pump inhibitor medicines (e.g. pantoprazole, lansoprazole, rabeprazole, esomeprazole). During treatment with these drugs, bacteria called Salmonella and Campylobacter have a low risk of gastrointestinal infection, may cause an increase.
- If you are taking a medicine containing nelfinavir (used for HIV infection).

### Use ERBINNA WITH CAUTION in the following conditions

If any of the following happen to you:

- In case of pain or indigestion during treatment with ERBINNA,
- In case of significant weight loss out of your control,
- If you start vomiting blood or food,
- If the stool is black (melena) or bloody,
- If you have severe liver problems,
- If you are at risk of fractures of hip, wrist or spine due to osteoporosis,
- If the amount of magnesium in your blood is low and treatment for this condition (Digoxin or magnesium in your blood, such as diuretics). If you use medication that may reduce the amount of magnesium levels in your blood.
- If you are going to undergo a diagnostic examination for neuroendocrine tumors.

Talk to your doctor straight away **IMMEDIATELY**.

If these warnings apply to you, even at any time in the past, please consult your doctor.

### ERBINNA with food and drink

There is no interaction with food and drink due to the way of use

### Pregnancy

*Consult your doctor or pharmacist before using the medicine*

Before you start using ERBINNA, ask your doctor if you are pregnant or inform them that you plan to stay. Your doctor will decide whether to use ERBINNA or not.

*Consult your doctor or pharmacist if you notice that you are pregnant during treatment.*

### Lactation

*Consult your doctor or pharmacist before using ERBINNA*

If you are breastfeeding, your doctor will decide whether to use ERBINNA or not.

### **Effects on ability to drive and use machines**

ERBINNA is not expected to affect your ability to drive and use machines. Dizziness and side effects such as visual disturbances (see Chapter 4) may be occurred. Therefore, Do not use the car and the machine if such side effects occur during your treatment.

### **Important information about some of the excipients present in ERBINNA**

ERBINNA contains less than 23 mg sodium in each ml. No negative effect expected related sodium.

### **ERBINNA with other medicinal products**

- Ketoconazole, itraconazole, posaconazole or voriconazole (used to treat infections caused by a fungus).
- Diazepam (used to treat anxiety).
- Phenytoin (used in epilepsy).
- Medicines that are used to thin your blood, such as warfarin or other vitamin K blockers.
- Cilostazol (used to treat intermittent claudication).
- Tacrolimus (in cases of organ transplantation).
- Digoxin (used to treat heart problems).
- Rifampicin (used to treat tuberculosis).
- Clopidogrel (used to prevent blood clots (thrombi)).
- May seen drug interaction in case of concomitant use with erlotinib (used to treat cancer).
  - If you are taking high doses of chemotherapy medication (methotrexate) to treat cancer, your doctor may temporarily stop your ERBINNA treatment.
- Concomitant use of omeprazole with drugs used for the treatment of HIV, such as saquinavir, atazanavir, and nelfinavir is not recommended.
- Tell your doctor if you have severe liver problems as dose reduction may be possible.

If your doctor prescribe antibiotics amoxicillin and clarithromycin together with ERBINNA to treat ulcers caused by Helicobacter pylori infection, it is very important that you tell your doctor about any other medication you are taking.

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

### **3.How to use ERBINNA ?**

#### **Instructions for proper use and dose / application frequency:**

The usual dose is 40 mg once a day.

Patients with Zollinger-Ellison syndrome (a condition that causes excessive acid secretion in the stomach)the usual dose for is 60 mg ERBINNA once a day.

Higher doses may be necessary and dose adjustment should be custom-made. Dose to be given is determined by the doctor.

**Use of administration and method:**

A doctor or nurse will give you ERBINNA slowly into the vein.

**Different age groups****Pediatric population :**

The experience with its use in children is limited.

**Geriatric population :**

Dose adjustment is not necessary for geriatric population.

**Special use conditions:**

For patients who cannot use ERBINNA capsules or tablets and for tube-fed patients through may be given by oral route.

**Hepatic failure :** Lower doses may be necessary in patients with hepatic impairment.

**Renal failure :** Dose adjustment is not necessary for patients with renal failure.

*If you think that the effect of ERBINNA is very strong or weak talk to your doctor or pharmacist.*

**If you use more ERBINNA than you should :**

*If you suspect ERBINNA has been given more than you should use, talk to your doctor.*

**If you forget to use ERBINNA**

Do not double-dose to compensate for forgotten doses.

**Effects that may occur when ERBINNA is discontinued**

There is no effect.

**4. Possible side effects**

Like all medicines, this medicine can cause side effects if you have hypersensitivity to any compound present in the formulation

**If you have any of the following, stop using ERBINNA and IMMEDIATELY tell your doctor or contact the nearest hospital emergency department:**

- Swelling of face, lips, tongue and / or throat, difficulty breathing, difficulty swallowing like allergic reactions (such as anaphylactic shock),
- Tissue disorders seen in the skin in the form of inflamed wounds or water collection and Stevens-Johnson syndrome.

- Symptoms of liver problems such as yellow skin, dark urine and fatigue.

If you have one of these, you have a serious allergy to ERBINNA. You may need urgent medical attention or hospitalization.

All of these very serious side effects are very rare.

The side effects in this section are classified according to their incidence. For this purpose the following frequency definitions are used:

Side effects are listed as shown in the following categories:

Very common ( $\geq 1/10$ ),  
Common ( $\geq 1/100$  to  $< 1/10$ ),  
Uncommon ( $\geq 1/1,000$  to  $< 1/100$ ),  
Rare ( $\geq 1/10,000$  to  $< 1/1,000$ ),  
Very rare ( $< 1/10,000$ ),  
Not known (cannot be estimated from the available data).

**Common:**

- Headache
- Effects on stomach or intestines: Diarrhea, constipation, abdominal pain, flatulence occurrence.
- Feeling sick (nausea) or being sick (vomiting)

**Uncommon:**

- Swelling of feet and wrists
- Insomnia
- Drowsiness, tingling sensation, drowsiness
- Dizziness (vertigo)
- Changes in blood tests to check how the liver works
- Rash, skin inflammation and / or itching, urticaria
- Feeling unwell and lack of energy

**Rare:**

- Agitation (irritability), irritability, depression
- Dry mouth, inflammation in the mouth
- Fungal infection of the gastrointestinal tract
- Decreased blood cell count (leukopenia, thrombocytopenia, agranulocytosis, pancytopenia)
- Serious liver problems (interstitial nephritis)
- Inflammation of the liver without jaundice or jaundice, liver failure
- Muscle pain, muscle weakness and joint pain
- Sensitivity to light, severe skin reactions
- Hair loss
- Hypersensitivity reactions (angioedema, fever, bronchospasm and anaphylactic shock)
- Excessive sweating
- Blurred vision, taste disturbance
- Reduction in blood sodium levels (may cause weakness, vomiting and cramps)

**Very rare:**

- Changes in blood count including agranulocytosis (white blood cell deficiency)
- Aggression
- Hallucinations
- Serious liver problems that cause liver failure and inflammation of the brain
- Muscle weakness
- Breast growth in men
- Sudden and severe onset of rash or blistering or shedding of the skin. High fever and joint pain (Erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis).

**Not known:**

- Intestinal inflammation (may cause diarrhea)
- Reduction in the amount of magnesium in the blood (If you are receiving treatment for more than 3 months with ERBINNA, the amount of magnesium in your blood may decrease. Low magnesium content may cause fatigue, involuntary muscle contractions, disorientation, contractions, dizziness or increased heart rate. If you have any of these symptoms, please tell your doctor immediately. Low amount of magnesium in your blood may cause decrease of potassium and calcium. Your doctor may require you to have regular blood tests to monitor your magnesium amount.)

In severe cases, in a few cases, especially in high doses of omeprazole, irreversible visual disturbances have been reported after intravenous treatment. However, no causal relationship between these symptoms and omeprazole treatment was found.

ERBINNA affects white blood cells and rarely causes immunodeficiency. If fever is accompanied by symptoms of reducing the overall condition as severe or if you have an infection with signs of infection like fever with neck, throat or mouth pain or difficulty urinating, consult your doctor as soon as possible; thus, your lack of white blood cells (agranulocytosis) can be eliminated by the blood test. It is important that you inform your doctor about your medication.

*If you experience any side effects not mentioned in this patient information leaflet, inform your doctor or pharmacist.*

**Reporting of suspected adverse reactions**

Talk to your doctor, pharmacist or nurse if you have any side effects located or not in patient information leaflet. In addition, notify the side effects you are experiencing to [www.titck.gov.tr](http://www.titck.gov.tr) site by clicking "Drug side effects notification" icon or by calling 0 800 314 00 08 numbered side effect statement line Turkey Pharmacovigilance Center (TÜFAM). By reporting side effects, you will contribute to learning more about the safety of the medicine you are using.

**5. How to store ERBINNA ?**

*Keep ERBINNA out of the sight and reach of children, in its package.*

Store at room temperature below 25°C, protect from light in original package.

Vials removed from their outer packaging, provided that they are protected from light, under normal room light. Can be stored for up to 24 hours.

Reconstituted solution for injections, can be stored for 4 hours at room temperature or for 12 hours in a refrigerator.

Your doctor or hospital will store ERBINNA in correct storage, preparation and administration are the responsibility of health personnel.

### **Use in accordance with expiration date**

Do not use ERBINNA if you notice that the pack is damaged or show signs of tampering.

Do not throw away any expired or unused medicines! Give to the collection system determined by the Ministry of Environment and Urbanism

**Marketing Authorisation Holder :** Biem İlaç San. ve Tic. A.Ş.

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Tandoğan / Çankaya – Ankara

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