

**PACKAGE LEAFLET: INFORMATION FOR THE USER**  
**Pugritex 10 mg & 20 mg Gastro-resistant Capsules**  
(omeprazole)

**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 symptoms 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 Pugritex Gastro-resistant Capsules are and what they are used for
2. What you need to know before you take Pugritex Gastro-resistant Capsules
3. How to take Pugritex Gastro-resistant Capsules
4. Possible side effects
5. How to store Pugritex Gastro-resistant Capsules
6. Contents of the pack and other information

**1. What Pugritex Gastro-resistant Capsules are and what they are used for**

Pugritex Gastro-resistant Capsules contains the active substance omeprazole. It belongs to a group of medicines called proton pump inhibitors. They work by reducing the amount of acid that your stomach makes.

Pugritex Gastro-resistant Capsules are used for treating the following conditions:-

**In adults:**

- ‘Gastro-esophageal reflux disease’ (GERD). This is where acid from the stomach escapes into the gullet (the tube which connects your throat to your stomach) causing pain, inflammation and heartburn
- ulcers in the upper part of the intestine (duodenal ulcer) or stomach (gastric ulcer)
- ulcers which are infected with bacteria called ‘*Helicobacter pylori*’. If you have this condition, your doctor may also prescribe antibiotics to treat the infection and allow the ulcer to heal
- ulcers caused by medicines called NSAIDs (Non-Steroidal Anti-Inflammatory Drugs). Pugritex Gastro-resistant Capsules can also be used to stop ulcers from forming if you are taking NSAIDs
- too much acid in the stomach caused by growth in the pancreas (Zollinger-Ellison syndrome)

**In children:**

*Children over 1 year of age and  $\geq 10$  kg*

- ‘Gastro-esophageal reflux disease’ (GERD). This is where acid from the stomach escapes into the gullet (the tube which connects your throat to your stomach) causing pain, inflammation and heartburn.  
In children, the symptoms of the condition can include the return of stomach contents into the mouth (regurgitation), being sick (vomiting) and poor weight gain.

*Children and adolescents over 4 years of age*

- Ulcers which are infected with bacteria called '*Helicobacter pylori*'. If your child has this condition, your doctor may also prescribe antibiotics to treat the infection and allow the ulcer to heal.

## **2. What you need to know before you take Pugritex Gastro-resistant Capsules**

### **Do not take Pugritex Gastro-resistant Capsules:**

- if you are allergic (hypersensitive) to omeprazole or any of the ingredients.
- if you are allergic to medicines containing other proton pump inhibitors (eg pantoprazole, lansoprazole, rabeprazole, esomeprazole).
- if you are taking a medicine containing nelfinavir (used for HIV infection).

If you are not sure, talk to your doctor or pharmacist before taking Pugritex Gastro-resistant Capsules.

### **Warnings and precautions**

Talk to your doctor before taking Pugritex Gastro-resistant Capsules.

Pugritex Gastro-resistant Capsules may hide the symptoms of other diseases. Therefore, if any of the following happen to you before you start taking Pugritex Gastro-resistant Capsules or while you are taking it, talk to your doctor straight away:

- you lose a lot of weight for no reason and have problems swallowing
- you get stomach pain or indigestion
- you begin to vomit food or blood
- you pass black stools (blood-stained faeces)
- you experience severe or persistent diarrhoea, as omeprazole has been associated with a small increase in infectious diarrhoea
- you have severe liver problems

If you take Pugritex Gastro-resistant Capsules on a long-term basis (longer than 1 year) your doctor will probably keep you under regular surveillance. You should report any new and exceptional symptoms and circumstances whenever you see your doctor.

Taking a proton pump inhibitor like Pugritex Gastro-resistant Capsules, 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 Pugritex Gastro-resistant Capsules:**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not take Pugritex Gastro-resistant Capsules if you are taking a medicine containing **nelfinavir** (used to treat HIV infection).

Tell your doctor if you are taking any of the following medicines:

- ketoconazole, itraconazole or voriconazole (used to treat infections caused by a fungus)
- digoxin (used to treat heart problems)
- diazepam (used to treat anxiety, relax muscles or in epilepsy)
- phenytoin (used in epilepsy) If you are taking phenytoin, your doctor will need to monitor you when you start or stop taking Pugritex Gastro-resistant Capsules

- medicines that are used to thin your blood, such as warfarin or other vitamin K blockers. Your doctor may need to monitor you when you start or stop taking Pugritex Gastro-resistant Capsules
- rifampicin (used to treat tuberculosis)
- atazanavir (used to treat HIV infection)
- tacrolimus (in cases of organ transplantation)
- St John's wort (*Hypericum perforatum*) (used to treat mild depression)
- cilostazol (used to treat intermittent claudication)
- saquinavir (used to treat HIV infection)
- clopidogrel (used to prevent blood clots (thrombi))
- erlotinib (used to treat cancer)
- 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 treatment with Pugritex Gastro-resistant Capsules

If your doctor has prescribed the antibiotics amoxicillin and clarithromycin as well as Pugritex Gastro-resistant Capsules to treat ulcers caused by *Helicobacter pylori* infection, it is very important that you tell your doctor about any other medicines you are taking.

#### **Pugritex Gastro-resistant Capsules with food, drink and alcohol**

You can take your capsules with food or on an empty stomach.

#### **Pregnancy and Breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Your doctor will decide whether you can take Pugritex Gastro-resistant Capsules during this time.

Your doctor will decide whether you can take Pugritex Gastro-resistant Capsules if you are breastfeeding.

#### **Driving and using machines:**

Pugritex Gastro-resistant Capsules is not likely to affect your ability to drive or to use machines. Side effects, such as dizziness and visual disturbances may occur (see section 4). If affected, you should not drive or use machines.

#### **Pugritex Gastro-resistant Capsules contains sucrose**

Pugritex Gastro-resistant Capsules contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars contact your doctor before taking this product.

### **3. How to take Pugritex Gastro-resistant Capsules**

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

Your doctor will tell you how many capsules to take and how long to take them for. This will depend on your condition and how old you are.

The recommended doses are given below.

#### Adults:

To treat symptoms of GERD such as **heartburn and acid regurgitation:**

- If your doctor has found that your food pipe (gullet) has been slightly damaged, the usual dose is 20 mg once a day for 4-8 weeks. Your doctor may tell you to take a dose of 40 mg for a further 8 weeks if your gullet has not yet healed.

- The usual dose once the gullet has healed is 10 mg once a day.
- If your gullet has not been damaged, the usual dose is 10 mg once a day.

To treat **ulcers in the upper part of the intestine** (duodenal ulcer):

- The usual dose is 20 mg once a day for 2 weeks. Your doctor may tell you to take the same dose for a further 2 weeks if your ulcer has not yet healed.
- If the ulcer does not fully heal, the dose can be increased to 40 mg once a day for 4 weeks.

To treat **ulcers in the stomach** (gastric ulcer):

- The usual dose is 20 mg once a day for 4 weeks. Your doctor may tell you to take the same dose for a further 4 weeks if your ulcer has not yet healed.
- If the ulcer does not fully heal, the dose can be increased to 40 mg once a day for 8 weeks.

To **prevent the duodenal and stomach ulcers** from coming back:

- The usual dose is 10 mg or 20 mg once a day. Your doctor may increase the dose to 40 mg once a day.

To treat duodenal and stomach **ulcers caused by NSAIDs** (Non-Steroidal Anti-Inflammatory Drugs):

- The usual dose is 20 mg once a day for 4–8 weeks.

To **prevent duodenal and stomach ulcers** if you are taking **NSAIDs**:

- The usual dose is 20 mg once a day.

To treat **ulcers caused by *Helicobacter pylori*** infection and to stop them coming back:

- The usual dose is 20 mg PUGRITEX Gastro-resistant Capsules twice a day for one week.
- Your doctor will also tell you to take two antibiotics among amoxicillin, clarithromycin and metronidazole.

To treat too much acid in the stomach caused by a **growth in the pancreas (Zollinger - Ellison syndrome)**:

- The usual dose is 60 mg daily.
- Your doctor will adjust the dose depending on your needs and will also decide how long you need to take the medicine for.

Use in children and adolescents:

To treat symptoms of GERD such as **heartburn and acid regurgitation**:

- Children over 1 year of age and with a body weight of more than 10 kg may take PUGRITEX Gastro-resistant Capsules. The dose for children is based on the child's weight and the doctor will decide the correct dose.

To treat **ulcers caused by *Helicobacter pylori*** infection and to stop them coming back:

- Children aged over 4 years may take PUGRITEX Gastro-resistant Capsules. The dose for children is based on the child's weight and the doctor will decide the correct dose.
- Your doctor will also prescribe two antibiotics called amoxicillin and clarithromycin for your child.

**Taking this medicine**

- It is recommended that you take your capsules in the morning.
- You can take your capsules with food or on an empty stomach.
- Swallow your capsules whole with half a glass of water. Do not chew or crush the capsules. This is because the capsules contain coated pellets which stop the medicine from being broken down by the acid in your stomach. It is important not to damage the pellets.

**What to do if you or your child has trouble swallowing the capsules**

- If you or your child have trouble swallowing the capsules:
- Open the capsules and swallow the contents directly with half a glass of water or put the contents into a glass of still (non-fizzy) water, any acidic fruit juice (e.g. apple, orange or pineapple) or apple sauce.
- Always stir the mixture just before drinking it (the mixture will not be clear). Then drink the mixture straight away or within 30 minutes.
- To make sure that you have drunk all of the medicine, rinse the glass very well with half a glass of water and drink it. The solid pieces contain the medicine - do not chew or crush them.

**If you take more Pugritex Gastro-resistant Capsules than you should:**

If you take more Pugritex Gastro-resistant Capsules than prescribed by your doctor, talk to your doctor or pharmacist straight away.

**If you forget to take Pugritex Gastro-resistant Capsules:**

Take another as soon as you remember, unless it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

**4. Possible side effects**

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

**If any of the following happen, stop taking this medicine and tell your doctor immediately or go to the emergency department at your nearest hospital:**

- Sudden wheezing, swelling of your lips, tongue and throat or body rash, fainting or difficulties in swallowing (severe allergic reaction).
- Reddening of the skin with blisters or peeling. There may also be severe blisters and bleeding in the lips, eyes, mouth, nose and genitals. This could be 'Stevens-Johnson syndrome' or 'toxic epidermal necrolysis'.
- Yellow skin, dark urine and tiredness which can be symptoms of liver problems.

Side effects may occur with certain frequencies, which are defined as follows:

Very common:	may affect more than 1 in 10 people
Common:	may affect up to 1 in 10 people
Uncommon:	may affect up to 1 in 100 people
Rare:	may affect up to 1 in 1,000 people
Very rare:	may affect up to 1 in 10,000 people
Not known:	frequency cannot be estimated from the available data

Other side effects include:

**Common side effects:**

- headache.
- Effects on your stomach or gut, diarrhoea, stomach pain, constipation, wind (flatulence).
- Feeling sick (nausea) or being sick (vomiting).

**Uncommon side effects:**

- Swelling of the feet and ankles.
- Disturbed sleep (insomnia).
- Dizziness, tingling feelings such as "pins and needles", feeling sleepy.
- Spinning feeling (vertigo).

- Changes in blood tests that check how the liver is working.
- Skin rash, lumpy rash (hives) and itchy skin.
- Generally feeling unwell and lacking energy
- Fracture of the hip, wrist or spine.

#### **Rare side effects:**

- Blood problems such as a reduced number of white cells or platelets. This can cause weakness, bruising or make infections more likely.
- Allergic reactions, sometimes very severe, including swelling of the lips, tongue and throat, fever, wheezing.
- Low levels of sodium in the blood. This may cause weakness, being sick (vomiting) and cramps.
- Feeling agitated, confused or depressed.
- Taste changes.
- Eyesight problems such as blurred vision.
- Suddenly feeling wheezy or short of breath (bronchospasm).
- Dry mouth.
- An inflammation of the inside of the mouth.
- An infection called “thrush” which can affect the gut and is caused by a fungus.
- Liver problems, including jaundice which can cause yellow skin, dark urine, and tiredness.
- Hair loss (alopecia).
- Skin rash on exposure to sunshine.
- Joint pains (arthralgia) or muscle pains (myalgia).
- Severe kidney problems (interstitial nephritis).
- Increased sweating.
- Inflammation in the gut (leading to diarrhoea).

#### **Very rare side effects**

- Changes in blood count including agranulocytosis (lack of white blood cells).
- Aggression.
- Seeing, feeling or hearing things that are not there (hallucinations).
- Severe liver problems leading to liver failure and inflammation of the brain.
- Sudden onset of a severe rash or blistering or peeling skin. This may be associated with a high fever and joint pains (Erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis).
- Muscle weakness.
- Enlarged breasts in men.

Pugritex Gastro-resistant Capsules may in very rare cases affect the white blood cells leading to immune deficiency. If you have an infection with symptoms such as fever with a **severely** reduced general condition or fever with symptoms of a local infection such as pain in the neck, throat or mouth or difficulties in urinating, you must consult your doctor as soon as possible so that a lack of white blood cells (agranulocytosis) can be ruled out by a blood test. It is important for you to give information about your medicine at this time.

#### **Frequency not known**

If you are on Pugritex Gastro-resistant Capsules 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. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium.

#### **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.

You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Pharmacovigilance Section  
Irish Medicines Board  
Kevin O'Malley House  
Earlsfort Centre  
Earlsfort Terrace  
IRL - Dublin 2  
Tel: +353 1 6764971  
Fax: +353 1 6767836  
Website: [www.imb.ie](http://www.imb.ie)  
e-mail: [imbpharmacovigilance@imb.ie](mailto:imbpharmacovigilance@imb.ie)

## 5. How to store PUGRITEX Gastro-resistant Capsules

- 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 label. The expiry date refers to the last day of that month.
- Do not store above 30°C.
- Store in the original package. Keep the bottle tightly closed, in order to protect from moisture.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

## 6. Contents of the pack and other information

What PUGRITEX Gastro-resistant Capsules contain:

- The active substance is omeprazole. Each gastro resistant capsule contains of 10mg or 20mg Omeprazole.

- The other ingredients are: Sugar spheres (sucrose and maize starch), Sodium starch glycollate Type A, Sodium laurilsulfate, Povidone K30, Potassium oleate, Oleic acid, Hypromellose, Methacrylic acid-ethyl acrylate copolymer, Triethyl citrate, Titanium dioxide (E171), Talc, Erythrosine (E127), Quinoline yellow (E104), Gelatin, Red Iron Oxide (E172) (10mg Capsules) or Indigo carmine (E132) (20mg Capsules). The printing ink on the capsules contains the following additional ingredients: Shellac, Polyvinylpyrrolidone, Sodium hydroxide and Titanium dioxide (E171).

What PUGRITEX Gastro-resistant Capsules look like and contents of the pack:

10 mg Capsules: have an orange body and red cap and are marked with O10  
20 mg Capsules: have an orange body and blue cap and are marked with O20

PUGRITEX Gastro-resistant Capsules are available in bottles of 14 Capsules.

**Marketing Authorisation Holder**

Laboratorios Davur, S.L.U, C/ Anabel Segura 11, Edificio Albatros B, 1a planta, Alcobendas,  
28108 Madrid, Spain

**Manufacturer**

Teva Pharma S.L.U  
Poligono Industrial Malpica  
Calle C, Numero 4  
50016 Zaragoza  
Spain

This medicinal product is authorised in the Member States of the EEA under the following names:

<i>Name of Member State</i>	<i>Name of medicinal product</i>
Ireland	Pugritex 10 mg & 20 mg Gastro-resistant Capsules
Italy	Pugritex 10 mg & 20 mg capsule rigide gastroresistenti

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