



**Read all of this leaflet carefully before you start taking this medicine**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, health care provider 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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist.

**In this leaflet:**

- a) What Esofag-D is and what it is used for
- b) Before you take Esofag-D
- c) How to take Esofag-D
- d) Possible Side Effects
- e) How to store Esofag-D
- f) Further information

**a. What Esofag-D is and what it is used for**

Esomeprazole contains a medicine called esomeprazole. This belongs to a group of medicines called 'proton pump inhibitors'. They work by reducing the amount of acid that your stomach produces.

Domperidone contain domperidone as the active ingredient, which belongs to a group of medicines called 'dopamine antagonists'.

**How Esofag D works**

Esomeprazole is used to treat the following conditions:

Adults and adolescents aged 12 years and above

- 'Gastroesophageal reflux disease' (GORD). 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 stomach or upper part of the gut (intestine) that 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.

Domperidone works by helping to move food faster through your food pipe (esophagus), stomach and gut. This is so that it does not stay in the same place for too long. It also helps stop food flowing the wrong way back up your food pipe. This medicine is for use in adults and children aged 16 years and over.

#### **b. Before you take Esofag D**

##### **Do not take Esomeprazole & Domperidone:**

If you have an allergy to:

- Any medicines containing esomeprazole, amoxicillin or clarithromycin
- Any ingredients listed at the end of the leaflet
- Any other similar medicines such as proton pump inhibitors, penicillins, cephalosporins or macrolide antibiotics. Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take Esomeprazole & Domperidone if you are taking any of the following medicines:

- Cisapride
- Pimozide
- Ergotamine
- Dihydroergotamine
- Astemizole
- Terfenadine
- Cilostazol
- Atazanavir
- Colchicine
- Simvastatin
- Lovastatin.

##### **Taking Esofag-D and Other medicines**

*Do not take Esomeprazole & Domperidone if you are taking the following medicines:*

- Cisapride, a medicine used to treat heartburn
- Pimozide, a medicine used to treat mood disorders
- Ergotamine or dihydroergotamine, medicines used to treat migraine headaches
- Astemizole or terfenadine, medicines used to treat hay fever and allergies
- Atazanavir, a medicine used to treat Human Immunodeficiency Virus (HIV)

- Cilostazol, a medicine used to treat intermittent claudication.
- Colchicine, a medicine used to treat gout
- Lovastatin or simvastatin, medicines used to treat high cholesterol

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

- Ketoconazole tablets or liquid for fungal infections.
- Antibiotics for infections (such as erythromycin)

### **Pregnancy and breast-feeding**

Before taking Esomeprazole & Domperidone, tell your doctor if you are pregnant or trying to get pregnant. Ask your doctor or pharmacist for advice before taking any medicine. Your doctor will decide whether you can take Esomeprazole & Domperidone during this time. It is not known if it passes into breast milk. Therefore, you should not take Esomeprazole & Domperidone if you are breastfeeding. If you have not told your doctor about any of the above, tell them before you start taking Esomeprazole & Domperidone.

### **c. How to take Esofag D**

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

- If your doctor has found that your food pipe (gullet) has been slightly damaged, the recommended dose is one Capsule of Esomeprazole & Domperidone once a day for 4 weeks. Your doctor may tell you to take the same dose for a further 4 weeks if your gullet has not yet healed.
- The recommended dose once the gullet has healed is one Capsule once a day.

It is gastro-resistant capsules are not recommended for children less than 12 years old.

- If you are taking this medicine for a long time, your doctor will want to monitor you (particularly if you are taking it for more than a year).
- If your doctor has told you to take this medicine as and when you need it, tell your doctor if your symptoms change.

You can take your capsules at any time of the day.

- You can take your capsules with food or on an empty stomach.
- Swallow your capsules whole with a drink 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.

#### **d. Possible side effects**

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Esomeprazole & Domperidone.

Esomeprazole & Domperidone helps most people with peptic ulcer and Helicobacter pylori infection, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- Diarrhoea, nausea or vomiting
- Headache
- Dizziness
- Constipation
- Loss of appetite
- Stomach pain
- Wind
- Dryness of the mouth or other body cavities
- Soreness of mouth or tongue
- "pins and needles"
- Metallic taste or other change in taste or smell.
- These side effects are usually mild.
- Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice the following:
  - Muscle pain or weakness
  - Increase in breast size (males)
  - Fever
  - Changes in sleep patterns
  - Mood changes, hallucinations, confusion or depression
  - Change in sexual function
  - Blurred vision, hearing disturbances
  - Hair loss
  - bleeding or bruising more easily than normal
  - Signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers

- Skin rash
- Blood in urine
- Tremor
- Convulsions or fits
- Overgrowth of yeast infections (thrush).

Do not take any medicine to stop the diarrhoea unless advised by your doctor. These are very serious side effects. If you have them, you may have had a serious reaction to one of the medicines in Esomeprazole & Domperidone. You may need urgent medical attention or hospitalization.

Tell your doctor if you notice anything else that is making you feel unwell. Some people may get other side effects while taking Esomeprazole & Domperidone. Do not be alarmed by this list of possible side effects. You may not experience any of them.

#### **e. How to store Esofag D**

Keep out of the reach and sight of children.

Do not store above 30°C.

Do not use Esofag D after the expiry date which is stated on the label/carton/bottle after EXP. The expiry date refers to the last day of the month.

Do not use Esofag D If you notice the visible signs of deterioration.

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

#### **f. Further information**

##### **What Esofag D contains**

The active substance is Esomeprazole enteric coated pellets, Domperidone sustained release pellets,

The other ingredients are: HEG Capsules shells of size '1'.

##### **What Esofag D looks like and contents of the pack**

Hard gelatin Capsules '1' size Blue/Clear transparent Micro Printed containing white & orange colored pellets.

Alu Alu strip pack of 3 x 10's capsules

#### **Name and full physical address of Marketing Authorization Holder and Manufacturing site**

##### **Marketing Authorization Holder**

**MICRO LABS LIMITED**

31, Race course road

Bangalore-560001

INDIA

**Manufacturer**

**MICRO LABS LIMITED**

No. 92, Sipcot Industrial Complex

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**Date of Revision**

May 2024