

JULPHASOLE CAPSULE

Lansoprazole (30mg)

What is in this leaflet

1. What Julphasole is used for
2. How Julphasole works
3. Before you take Julphasole
4. How to take Julphasole
5. While you are using Julphasole
6. Side effects
7. Storage and Disposal of Julphasole
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What Julphasole is used for

Jusphasole is used for treatment of gastric ulcer, duodenal ulcer, stomal ulcer (an intestinal ulcer near the opening (stoma) between the stomach and the jejunum), reflux esophagitis (inflammation of the esophagus caused by the backflow of stomach contents) and Zollinger-Ellison syndrome (excess acid production in the stomach caused by growth in the pancreas).

Eradication of bacteria *Helicobacter pylori* from the upper gastrointestinal tract in people with peptic ulcer (duodenal or benign gastric ulcer) when used in combination with appropriate antibiotics.

How Julphasole works

The active ingredient in your medicine is lansoprazole, which is a proton pump inhibitor. Proton pump inhibitors reduce the amount of acid that your stomach makes.

Before you take Julphasole

- When you must not take it

If you are allergic (hypersensitive) to lansoprazole or any of the other ingredients of Julphasole

Like other benzimidazole medicines, lansoprazole is better to be avoided during pregnancy and lactation (unless considered essential) until further research studies are available.

- Before you start to take it

Your doctor may arrange some test to diagnose for gastric cancer before

prescribing lansoprazole because lansoprazole can mask the symptoms and delay the diagnosis.

Please tell your doctor if you have serious liver disease.

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

If you are suffering from stomach (gastro-duodenal) ulcers, the possibility of infection caused by bacteria *Helicobacter pylori* should be considered.

If your doctor has given you Julphasole in addition to antibiotics intended for the treatment of *Helicobacter pylori* infection please also read the package leaflets of these medicines carefully.

If you take Julphasole 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.

Very rarely cases of inflammation of the colon have been reported in people taking lansoprazole.

Therefore, in the case of severe and/or persistent diarrhoea, discontinuation of therapy should be considered.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

In particular tell your doctor if you are taking medicines containing any of the following active substances as Julphasole may affect the way these drugs work:

- Atazanavir (used to treat viral infections)
- Ketoconazole and itraconazole, (used to treat fungal infections)
- digoxin (used to treat heart problems)

- theophylline (used to treat asthma)
- tacrolimus (used to prevent organ transplant rejection)
- fluvoxamine (used to treat depression and other psychiatric diseases)
- antacids (used to treat heartburn or acid regurgitation)
- sucralfate (used for healing ulcers)

How to use Julphasole

- How much to use

Usually for adults, take one capsule (30 mg of lansoprazole) orally once a day.

In duodenal ulcer, 30 mg once daily for 4 weeks.

In gastric ulcer and stomal ulcer, 30 mg once daily for 8 weeks.

In reflux esophagitis, 30 mg once daily for 4-8 weeks.

In Zollinger-Ellison syndrome, the dosage should be adjusted according to the signs and symptoms.

Eradication of *H. pylori* :

The following combinations have been shown to be effective over 7 days.

Lansoprazole capsule 30 mg twice daily plus two of the following antibiotics : amoxicillin 1g twice daily or metronidazole 400mg twice daily and clarithromycin 250-500mg twice daily.

The best eradication results are obtained when clarithromycin is combined with either amoxycillin or metronidazole. When used in combination with the recommended antibiotics, lansoprazole is associated with H-pylori eradication rates of up to 90% .

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Julphasole for as long as your doctor recommended.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Julphasole.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor or pharmacist.

Do not give Julphasole to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use

machines and contact your doctor immediately.

Side effects

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

Tell your doctor immediately if you experience any of the following symptoms:

- Hypersensitivity:

Rash and itching (pruritis) may infrequently occur. In such a case, lansoprazole should be discontinued.

- Hepatic (liver)

If any abnormality is observed, such appropriate measures as discontinuation of lansoprazole should be taken.

Since the changes of liver function test may infrequently occur, close observation should be made.

- Blood:

Reduction in red blood cell which can make the skin pale and cause weakness or breathlessness (Anemia), leukopenia (low white blood cell count) or eosinophilia (an abnormal increase in the number of a specific type of white blood cell) may infrequently occur.

Reduction in blood platelets, which increases risk of bleeding or bruising (Thrombocytopenia) may rarely occur.

- Gastrointestinal:

Constipation, diarrhea, dry mouth or abdominal distension may infrequently occur.

- Psychoneurotic:

Headache, sleepiness may infrequently occur.

Insomnia and dizziness may rarely occur.

- Others:

Fever or elevation of total cholesterol and uric acid may infrequently occur.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting)

Storage and Disposal of Julphasole

- Storage

Keep medicine out of the reach and sight of children.

Store below 25°C.

- Disposal

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.

Product Description

- What it looks like

Hard gelatin capsules, containing white to pale brownish-white enteric coated pellets in capsule with maroon-opaque cap and natural transparent body.

- Ingredients

- Active ingredient

The active substance is Lansoprazole.

Each capsule contains 30 mg Lansoprazole.

- Inactive ingredients

The other ingredients are Magnesium carbonate, sugar spheres, sucrose, maize starch, hydroxypropyl cellulose, methacrylic acid copolymer, talc fine powder, titanium dioxide, polyethylene glycol, polysorbate and aerosol.

- MAL Number

MAL08111779A

Manufacturer

Gulf Pharmaceutical Industries
(Julphar)
Digdaga, Airport Street
P.O.Box 997,
Ras Al Khaimah,
United Arab Emirates
Tel: (9717) 2461461
Fax: (9717) 2462462

Product Registration Holder

Averroes Pharmaceuticals Sdn. Bhd.
11E, Level 5, Block 1
Worldwide Business Center
Jalan 13/50, Section 13
40000 Shah Alam, Selangor
Malaysia

Date of revision

06/10/2015

Serial Number

BPFK(R4/1)210915/00319