

# Peptazol<sup>®</sup>

## Lansoprazole Anti-ulcerative

### Composition:

Each capsule contains 30 mg Lansoprazole.

### Pharmacological Properties:

*Peptazol* has an anti-ulcer properties through specific inhibition of the enzyme system of hydrogen / Potassium adenosine triphosphatase ( $H^+/K^+ATPase$ ) proton pump of the gastric parietal cells.

It reduces the gastric acid secretion whatever the nature of the stimulus. The single daily dose of 30 mg *Peptazol* taken orally produces rapid and effective inhibition of the gastric acid secretion.

After taking 30 mg the acid peak after stimulation is decreased by around 80 %, 24 hours after the last dose of a 7 days treatment, the stimulated acid output is continuously decreased by 51 %.

The endoscopic ulcus rate (healing rate) of the duodenal ulcer is 75 % in 2 weeks and 95 % in 4 weeks; that of peptic esophagitis is 80 % after 4 weeks of treatment and 95 % after 8 weeks.

### Pharmacokinetics:

#### Absorption and Distribution:

After oral dose of *Peptazol*, absorption is rapid, the maximum concentration is achieved in around 1.5 hours. The concomitant absorption of food reduces the bioavailability.

The protein binding of *Peptazol* is 97 %.

#### Metabolism and Elimination:

The plasmatic elimination half life is around 1.4 hours. This is not modified in the course of treatment. Lansoprazole is eliminated completely after hepatic biotransformation.

The metabolites identified in the plasma are sulphonic, sulphuric and 5-hydroxylated derivatives of Lansoprazole. These metabolites are without notable activity and lack particular toxicity. Elimination is principally biliary; urinary elimination in the form of hydroxylated derivatives represents 15 to 30% of the administered dose.

The pharmacokinetic profile is not modified in the elderly patients.

### Indications:

*Peptazol* is effective in the treatment of acid related disorders of the upper gastro - intestinal tract, with the benefit of rapid symptoms relief in :

- Duodenal ulcer
- Gastric ulcer
- Reflux esophagitis
- Peptic lesions unresponsive to conventional therapy
- Zollinger-Ellison syndrome (and other hypersecretory conditions).

### Dosage and Administration:

The capsules should be swallowed whole with water. Do not crush or chew.

**Gastric ulcer :** One capsule 30 mg *Peptazol* once daily in the morning for 8 weeks. Healing usually occurs within 8 weeks.

**Duodenal ulcer :** One capsule 30 mg *Peptazol* once daily in the morning for 4 weeks.

**Reflux esophagitis :** One capsule 30 mg *Peptazol* once daily for 4 weeks. The majority of patients will be healed after the first treatment course. For those patients not fully healed by this time, a further 4 weeks treatment course at the same dosage should be given.

**Zollinger-Ellison syndrome (and other hypersecretory conditions) :** Initially two capsules 30mg once daily adjusted according to response; daily doses of four capsules 30mg or more given in two divided doses.

**Peptic lesions unresponsive to conventional therapy :** One capsule 30 mg *Peptazol* once daily for 4 weeks should be given, further 4 weeks treatment course can be extended for patients who remain unhealed. In individual cases a dose of 60 mg once daily may be necessary.

### Contra-indications:

- Known hypersensitivity to Lansoprazole.
- Breast feeding.

### Precautions:

Like other gastric anti-secretory medicaments, Lansoprazole can favour the development of intragastric bacteria by decrease of the volume and the acidity of the gastric juice; Long - term treatment with Lansoprazole cannot be recommended at this time since clinical experience is limited.

- **In children :** The efficiency and the tolerance of the product have not been studied.
- **Elderly patients :** No dosage adjustment is necessary.
- **Hepatic and renal impairment :** No dosage adjustment is necessary.
- **Pregnancy :** Although no teratogenic or fetotoxic effects had been demonstrated on animal experiments, it is unadvisable to use Lansoprazole during the first trimester. Prescription should also be avoided during the remaining months of pregnancy unless absolutely necessary.
- Lansoprazole should be used with caution in patients with liver disease.
- Before treatment the presence of gastric malignancy should be excluded.

### Side effects:

*Peptazol* is generally well tolerated. Rare cases of transitory complaints including diarrhea, constipation, nausea and headache have been reported.

### Drug interactions:

Particular attention should be paid to patients receiving diazepam, phenytoin, theophylline and antivitamin K.

### Presentations:

*Peptazol* is available in capsules of 30 mg Lansoprazole.

#### This is a medicament

- A 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 experts in medicine, its 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 medicaments out of the reach of children

Council of Arab Health Ministers  
Union of Arab Pharmacists

Manufactured by **SPIMACO**

Al-Qassim Pharmaceutical Plant,  
Saudi Pharmaceutical Industries & Medical Appliances Corporation,  
Saudi Arabia

'Peptazol' is a trade mark

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