LANZORX

Gastro-resistant Lansoprazole Capsules BP 30 mg

Composition:
Each hard gelatin capsule contains :
Lansoprazole BP 30 MG
(As enteric coated granules)
Excipients Q.S: Approved colours used in empty capsule shells.

PHARMACODYNAMIC PROPERTIES :
Lanzorx [Lansoprazole] is a gastric proton pump inhibitor. It inhibits the final stage of gastric acid formation by inhibiting the activity of H+/K+ ATPase of the parietal cells in the stomach. The inhibition is dose dependent and reversible, and the effect applies to both basal and stimulated secretion of gastric acid.
Lanzorx [Lansoprazole] is concentrated in the parietal cells and becomes active in their acidic environment, where it reacts with the sulfhydryl group of H+/K+ATPase causing inhibition of the enzyme activity.

PHARMACOKINETIC PROPERTIES :
Lanzorx [Lansoprazole] is a racemate of two active enantiomers that are biotransformed into the active form in the acidic environment of the parietal cells. As lansoprazole is rapidly inactivated by gastric acid, it is administered orally in enteric-coated forms for systemic absorption.

ABSORPTION AND DISTRIBUTION :
Lanzorx [Lansoprazole] exhibits high (80-90%) bioavailability with a single dose. Peak plasma levels occur within 1.5 to 2.0 hours. Intake of food slows the absorption rate of Lanzorx [Lansoprazole] and reduces the bioavailabilty by about 50%. The plasma protein binding is 97%.

BIOTRANS FORMATION AND ELIMINATION :
Lanzorx [Lansoprazole] is extensively metabolised by the liver and the metabolites are excreted by both the renal and biliary route. The metabolism of Lanzorx [Lansoprazole] is mainly catalysed by the enzyme Cytochrome P450. The enzyme Cytochrome P450 family also contributes to the metabolism. The plasma elimination half-life ranges from 1 to 2 hours following single or multiple doses in healthy subjects. There is no evidence of accumulation following multiple doses in healthy subjects. Sulphone, sulphide and 5-hydroxyl derivatives of lansoprazole have been identified in plasma. These metabolites have very little or no antisecretory activity.
A study with 14C labelled lansoprazole indicated that approximately one-third of the administered radiation was excreted in the urine and two-thirds was recovered in the faeces.

PHARMACOKINETIC IN ELDERLY PATIENTS :
The clearance of Lanzorx [Lansoprazole] is decreased in the elderly, with elimination half-life increased approximately 50% to 100%. Peak plasma levels were not increased in the elderly.

PHARMACOKINETIC IN PAEDIATRIC PATIENTS :
The evaluation of the pharmacokinetics in children aged 1 —17 years of age showed a similar exposure as compared to adults with doses of 15 mg for those below 30 kg of weight and 30 mg for those above.

THERAPEUTIC INDICATIONS :
Treatment of duodenal and gastric ulcer.
Treatment of reflux oesophagitis.
Prophylaxis of reflux oesophagitis.

Eradication of Helicobacter pylori (H. pylori) concurrently given with appropriate antibiotic therapy for treatment of H.pylori-associated ulcers.
Treatment of NSAID - associated benign gastric and duodenal ulcers in patients requiring continued NSAID treatment.
Prophylaxis of NSAID - associated gastric ulcers and duodenal ulcers in patients at risk requiring continued therapy.
Symptomatic gastroesophageal reflux disease

Pharmacology and method of administration :
Lanzorx [Lansoprazole] is usually given orally as capsules, dispersible tablets, or suspension containing enteric-coated granules. Once daily regimen are taken before food in the morning. For the relief of acid-related dyspepsia. Intermittent courses of Lamont [Lansoprazole] may be given in doses of 15 or 30 mg once daily, for 2 to 4 weeks. In the treatment of gastro-oesophageal reflux disease the dose is 15 to 30 mg once daily for 4 to 8weeks; thereafter maintenance therapy can be continued with 15 or 30 mg once daily according to response. Lanzorx [Lansoprazole] is given for the treatment of peptic ulcer disease in the UK in doses of 30 mg once daily. Treatment is continued for 2 to 4 weeks for duodenal and 4 to 8 weeks for gastric ulcer. In USA, a dose of 15 mg daily for 4 weeks is recommended for duodenal ulcer, and 30 mg once daily is given for upto 8 weeks for gastric ulceration. When appropriate, 15 mg daily may be used as maintenance therapy for the prevention of relapse of duodenal ulcer.
Lanzorx [Lansoprazole] may be combined with antibacterials in one-week triple therapy regimen for the eradication of Helicobacterpylori. Inpatients with NSAID-associated ulceration a dose of 30 mg daily for 4 to 8 weeks is recommended; 15 to30 mg daily may be used as prophylaxis for patients who require continued NSAID treatment. In the treatment of pathological hypersecretory state such as the ZollingerEllison syndrome the initial dose is 60 mg once daily, adjusted as required doses of up to 90 mg twice daily have been used. Daily doses greater than 120 mg should be given in divided doses. In USA, children aged from 1 to 11 years may be given Lanzorx [Lansoprazole] for the short-term treatment of erosive oesophagitis and symptomatic gastro-oesophageal reflux disease. Children weighing 30 kg or less should be given Lanzorx [Lansoprazole] 15 mg once daily, and those weighing more than 30 kg are given 30 mg once daily, for up to 12weeks. Doses of up to 30 mg twice daily have been used. In children aged from 12 to 17 years, Lanzorx [Lansoprazole] 30 mg be given once daily for up to 8 weeks may be usedfor erosive oesophagitis, and 15 mg once daily for upto 8 weeks may be used for symptomatic gastro esophageal reflux disease.

CONTRA INDICATIONS :
Hypersensitivity to the active substance or to any of the excipients Lanzorx [Lansoprazole] should not be administered with atazanavir. Special warnings and precautions for use:
In common with other anti-ulcer therapies, the possibility of malignant gastric tumour should be excluded when treating a gastric ulcer with Lanzorx [Lansoprazole] because it can mask the symptoms and delay the diagnosis. Lanzorx [Lansoprazole] should be used with caution in patients with moderate and severe hepatic dysfunction. In patients suffering from gastro-duodenal ulcers, the possibility of H. pylori infection as an etiological factor should be considered. If Lanzorx [Lansoprazole] is used in combination with antibiotics for eradication therapy of H.pylori, then the instructions for the use of these antibiotics should also be followed. Very rarely cases of colitis have been reported in patients taking Lanzorx [Lansoprazole]. Therefore, in the case of severe or persistent diarrhoea, discontinuation of therapy should be considered. The treatment for the prevention of peptic ulceration of patients in need of continuous NSAID treatment should be restricted to high risk patients (e.g. previous gastrointestinal bleeding, perforation or ulcer, advanced age, concomitant use of medication known to increase the likelihood of upper GI adverse events [e.g. corticosteroids or anticoagulants], the presence of a serious co-morbidity factor or the prolonged use of NSAID maximum recommended doses). For patients expected to be on prolonged treatment or who take PPIs with digoxin or drugs that may cause hypomagnesaemia (e.g., diuretics). Health care professionals should consider measuring magnesium levels before starting PPI treatment and periodically during treatment.Proton pump

inhibitors, especially if used in high doses and over long durations (>1 year), may modestly increase the risk of hip, wrist and spine fracture, predominantly in the elderly or in presence of other recognised risk factors. Proton pump inhibitors are associated with very infrequent cases of SCLE. If lesions occur, especially in sun-exposed areas of the skin, and if accompanied by arthralgia, the patient should seek medical help promptly.
As Lanzorx [Lansoprazole] contains sucrose, patients with rare hereditary problems of fructose intolerance, glucose galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine. Fertility, Pregnancy and lactation.

PREGNANCY:
For Lanzorx [Lansoprazole], no clinical data on exposed pregnancies are available. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development.
Therefore, the use of Lanzorx [Lansoprazole] during pregnancy is not recommended.

BREASTFEEDING
It is not known whether Lanzorx [Lansoprazole] is excreted in human breast milk. Animal studies have shown excretion of Lanzorx [Lansoprazole] in milk.
A decision on whether to continue/discontinue breast-feeding or to continue/discontinue therapy with Lanzorx [Lansoprazole] should be made taking into account the benefit of breastfeeding to the child and the benefit of Lanzorx [Lansoprazole] therapy to the woman.

OVERDOSE:
The effects of overdose on Lanzorx [Lansoprazole] in humans are not known (although the acute toxicity is likely to be low) and consequently, instruction for treatment cannot be given. However, daily doses of up to 180 mg of Lanzorx [Lansoprazole] orally and up to 90 mg of Lanzorx [Lansoprazole] intravenously have been administered in trials without significant undesirable effects.
In the case of suspected overdose the patient should be monitored. Lanzorx [Lansoprazole] is not significantly eliminated by haemodialysis, If necessary, gastric emptying, charcoal and symptomatic therapy is recommended.

STORAGE
Store in cool and dry place. Protect from light and moisture.

Presentation:
Alu/Alu blister 4 x 7 capsules.

KEEP MEDICINE OUT OF REACH OF CHILDREN.