Lansoprazole

COMPOSITION

Lanso® 30 : Each capsule contains Lansoprazole USP 30 mg as enteric coated pellets.

PHARMACOLOGY

Lansoprazole is a benzimidazole sulfoxide derivative that produces long lasting inhibition of gastric acid secretion by inactivating parietal cell H^+/K^+ ATPase. Lansoprazole is rapidly and extensively absorbed (85%) from the gastrointestinal tract when administered as enteric coated pellets. There is little or no pre systemic metabolism. Absolute bioavailability of Lansoprazole from this form is 85% in healthy volunteers. Lansoprazole is rapidly distributed throughout the body, with a small volume of distribution because it is almost completely bound to plasma protein. Lansoprazole is eliminated primarily by hepatic metabolism, the metabolites being excreted both via the bile and in urine.

Summary of pharmacology of Lansoprazole is as follows:

Oral absorption	85%
Presystemic metabolism	Negligible
Mean plasma half life	1.5 hour
Volume of distribution	24 ± 8 L
Plasma protein binding	97 - 99%
	Presystemic metabolism Mean plasma half life Volume of distribution

INDICATION AND USES

Lansoprazole is indicated for:

- Short term treatment of active duodenal ulcer
- · Maintenance of healed duodenal ulcers
- · Short term treatment of active benign gastric ulcers
- · Short term treatment of active erosive esophagitis
- · Maintenance of healing of erosive esophagitis
- Pathological hypersecretory conditions including Zollinger- Ellison Syndrome
- H. pylori eradication to reduce the risk of duodenal ulcer recurrence

DOSAGE AND ADMINISTRATION

The most widely used dosage is 30 mg daily, occasionally 60 mg may be needed. Doses of up to 180 mg daily have been used to control acid output in patients with the Zollinger- Ellison Syndrome and 15 mg has been used as a maintenance dose.

DRUG INTERACTION

Lansoprazole appears to be a selective inhibitor of the cytochrome P-450 monooxygenase system; there may be an effect on hepatic clearance, but there have been no reports to date of clinically relevant interactions. There is some uncertainty over the effect of Lansoprazole on the oral combined contraceptive pill. Further assessment is currently underway. Physiological changes similar to those found with Omeprazole are likely to take place because of the reduction in gastric acid, which is likely to influence the bacterial colonization of the stomach and duodenum and also vitamin B12 absorption.

SIDE EFFECT

Generally mild and transient, including gastrointestinal disturbances, headache, dizziness, malaise, dry or sour mouth or throat, and alterations in liver function test values.

USE IN CHILDREN

No pediatric experience of Lansoprazole has been acquired.

USE IN PREGNANCY

Lansoprazole should be avoided in pregnancy unless there are compelling reasons.

CONTRAINDICATION

Lansoprazole is contraindicated in patients with known hypersensitivity to any component of the formulation.

STORAGE

Keep away from light and moisture. Store below 30°C.

HOW SUPPLIED

Lanso® 30: Box containing 30 capsules in Alu-Alu blister pack.

Manufactured by

