For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only

LIMZER

(Enteric Coated Omeprazole 20 mg and Domperidone SR 30 mg capsules)

DESCRIPTION

LIMZER, brand of Enteric coated Omeprazole 20 mg and Domperidone SR 30 mg Capsules, is chemically a combination of 5-Methoxy-2-[[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl] sulfinyl]-1H-benzimidazole & 5-chloro-1-[1-[3-(2,-3-dihydro-2-oxo-1H-benzimidazol-1-yl]propyl]-4-piperidinyl)-1,3-dihydro-2H-benzimidazol-2-one.

COMPOSITION

LIMZER

Each capsule contains :

Omeprazole BP/Ph.Eur (As enteric coated pellets)	20 mg
Domperidone BP/Ph.Eur (As sustained release pellets)	30 mg
Excipients	q.s.

INACTIVE INGREDIENTS

Non Pareil seeds (18-20) $MgCO_3$ and HPMC Coated, Hypromellose E 15 BP/Ph. Eur, Hypromellose E 5 BP/Ph. Eur, Purified Talc BP/Ph. Eur, Methacrylic Acid and Ethyl Acrylate Copolymer Dispersion USP, Sodium hydroxide BP/Ph.Eur, Glycerol monostearate 40 - 55 Ph. Eur, Polysorbate 80 BP/Ph.Eur, Magnesium stearate BP/Ph.Eur, Hypromellose Pthalate (HP 55) BP/Ph.Eur, Dibutyl sebacate USP, Non pareil seeds (18 - 20), Colloidal Anhydrous Silica BP/Ph. Eur, Ethyl cellulose (10 cps) USP, Triacetin USP-NF, Ferric oxide (yellow) USP-NF, Ferric oxide (red) USP-NF, Titanium Dioxide BP/Ph. Eur, Methyl Alcohol USP, Dichloromethane BP/Ph.Eur

PHARMACOLOGY

Omeprazole belongs to a new class of antisecretory compounds, the substituted benzimidazoles, that do not exhibit anticholinergic or H_2 histamine antagonist properties, but that suppress gastric acid secretion by specific inhibition of H^+/K^+ ATPase enzyme system at the secretory surface of the gastric parietal cells. It inhibits the proton pump, which is the final step in the gastric acid secretion.

Domperidone is a dopamine antagonist, which works as an upper gastrointestinal prokinetic and increases the tone of the lower esophageal sphincter and enhances gastric emptying. It does not produce dopamine antagonistic effects on central nervous system, probably because it fails to cross the blood brain barrier. It facilitates gastrointestinal smooth muscle activity by inhibiting dopamine at the D1 receptors. Domperidone effectively increases esophageal peristalsis and lower esophageal sphincter pressure (LESP), increases gastric motility and peristalsis, enhances gastro-duodenal coordination and consequently facilitates gastric emptying.

Domperidone is usually administered before meals as 10-20 mg 2-3 times a day. Administration of domperidone (30mg) as sustained release pellets enables once daily administration of the drug. This improves the patient compliance without compromising on the efficacy.

PHARMACOKINETICS

Omeprazole :

Enteric coated Omeprazole 20 mg and Domperidone SR 30 mg Capsules contain omeprazole as enteric coated pellets (as omeprazole is acid-labile), so the absorption begins only after the pellets leave the stomach. Absorption is rapid with peak plasma levels occurring within 0.5-3.5 hours. Peak plasma concentrations of omeprazole & AUC are approximately proportional to doses upto 40 mg. Absolute bioavailability is about 30-40% of doses of 20-40 mg, due in large part to presystemic metabolism. The plasma half life is 0.5 to 1 hour and the total body clearance is 500-600 ml/min. Protein binding is approximately 95%.

Following single dose oral administration, little if any unchanged drug is excreted in the urine. The majority of the drug is eliminated (77%) in urine as at least six metabolites. Two of the metabolites have been identified as hydroxyomeprazole & the corresponding carboxylic acid. The remaining part of the drug is recoverable in the faeces. There is significant biliary excretion of the metabolites of omeprazole. Three metabolites have been identified in the plasma-sulfide and sulfone derivatives of omeprazole and hydroxyomeprazole. These metabolites have very little or no antisecretary activity.

Domperidone :

Domperidone is absorbed from the gastrointestinal tract and undergoes extensive first pass hepatic and gut wall metabolism, which results in an oral bioavailability of 13% to 17%. Total plasma clearance is approximately 700ml/min. The elimination half-life following IV administration is approximately 7.5 hours, while following oral administration half-life is approximately 14 hours. It is secreted in the bile mainly as active metabolites.

SPECIAL POPULATIONS

Pregnant women :

There are no adequate and well-controlled studies in pregnant women. Sporadic reports have been received of congenital abnormalities occurring in infants born to women who have received Omeprazole during pregnancy. Safe use of domperidone in pregnancy has not been established, although studies in animals have not demonstrated teratogenic effects. Therefore, Enteric Coated Omeprazole and Domperidone SR Capsules should be used in pregnancy only if the potential benefit justifies the potential risk to the foetus.

Nursing mothers :

Omeprazole and its metabolites are excreted in the milk of rat. It is not known whether Omeprazole is excreted in human milk. Domperidone is excreted in breast milk but at very low levels. Because many drugs are excreted in human milk, because of the potential for serious adverse reactions in nursing infants from Omeprazole and because of the potential for tumorigenicity shown for Omeprazole in rat carcinogenicity studies, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Patients With Renal Impairment & the elderly :

No dosage adjustment is necessary for patients with renal impairment or for the elderly.

Actual Size : 125 mm X 180 mm / Front Side

Product Name : **Limzer (Uganda)**	
Packaging Material : Pack Insert (Front & Back Side)	
Location : Ambernath	Version No.: 01
Size : 125 x 180 mm (L x H)	
No. of Colour : 01 ■ Black	
Artwork No.: ACE0696L/01	SAP Code: 2008548
Substrate : White rectangular piece of Maplitho paper	
Drawing No. : NA	
Specification : 60 GSM	
Pharmacode : NA	
Any other Requirement : Final Folding Size : 62.5 x 45 mm	

Change History :

1) C/FI/18/001 - Change of name from Inventia Healthcare Private Limited to Inventia Healthcare Limited
2) CC/RA/2019/77 -
   - I) Limzer - Uganda Separate Artwork as limited (delete from OTC)
   - II) Dimension Changed from 250 x 180 to 125 x 180mm
   - III) Label claim change from BP to BP/Ph.Eur
   - IV) Maharashtra word added in inventia address
   - V) New Mega Logo & address
   - VI) Mega artwork code incorporate
   - VII) Text modified
   - VIII) other than English Language deleted

INDICATIONS
Enteric Coated Omeprazole and Domperidone SR Capsules combines Omeprazole, a proton pump inhibitor, which inhibits the secretion of acid in the stomach and domperidone, a dopamine antagonist which works as an upper gastrointestinal prokinetic agent. It is useful in the treatment of

1. Gastroesophageal reflux disease (GERD), and
2. Dyspepsia caused by gastroparesis and gastroesophageal reflux.

CONTRAINDICATIONS
Hypersensitivity to any of the components.

WARNING
Carefully read the instructions before use.
Do not exceed prescribed dose.
Keep out of reach of children.

PRECAUTIONS
In patients with severe liver impairment, the liver enzymes should be monitored regularly during treatment with Omeprazole, especially on long term use. If a rise in liver enzymes is observed, Enteric Coated Omeprazole and Domperidone SR Capsules should be discontinued. Prior to treatment, malignant disease of the oesophagus or stomach should be excluded as the treatment with Enteric Coated Omeprazole and Domperidone SR Capsules may alleviate the symptoms of malignant diseases and could delay diagnosis.

ADVERSE EFFECTS
The components of Enteric Coated Omeprazole and Domperidone SR Capsules, Omeprazole and domperidone, are generally very well tolerated. The reported adverse effects include headache, upper abdominal pain, diarrhoea, constipation, flatulence, eructation, insomnia, hyperglycaemia, pruritus, skin rash, asthenia, back pain, chest pain, neck pain, flu syndrome, infection, migraine, constipation, dyspepsia, gastroenteritis, rectal disorder, vomiting, hyperlipemia, pain, nausea, dizziness, anxiety, hypertonia, bronchitis, increased cough, dyspnoea, pharyngitis, rhinitis, sinusitis, upper respiratory tract infection, urinary frequency, urinary tract infection, a rise in serum prolactin which may be associated with galactorrhoea, less frequently with gynaecomastia, breast enlargement or soreness and are rarely observed.
There have been rare reports of blurring of vision, peripheral oedema, fever and isolated cases of urticaria, angioedema, depression or myalgia subsiding after termination of therapy, increased liver values and elevated triglyceride levels, acute extrapyramidal dystonic reactions including rare instances of oculogyric crises, occasional rashes, and rare reports of decreased libido and other allergic phenomenon and rare cases of anaphylaxis have also been reported.
Inform your doctor in case of any adverse reactions related to drug use.

DRUG INTERACTIONS
Omeprazole may reduce or increase the absorption of drugs whose bioavailability is pH dependent (e.g. Ketoconazole).

An interaction of Omeprazole with other drugs which are metabolised by the same enzyme system (Cytochrome P450) cannot be excluded. However no clinically significant interactions were observed in specific tests with a number of such drugs, namely carbamazepine, caffeine, diazepam, Diclofenac, digoxin, ethanol, glibenclamide, metoprolol, nifedipine, phenprocoumon, phenytoin, theophylline, warfarin and an oral contraceptive.

Domperidone may alter the peripheral actions of dopamine agonists such as bromocriptine, including its hypoprolactinaemic action. The actions of domperidone may be antagonised by antimuscarinic and opioid analgesics.

Domperidone may enhance the absorption of concomitantly administered drugs, especially in patients with delayed gastric emptying due of its ability to reduce the gastric emptying time.

OVERDOSAGE AND TREATMENT
Capsules if consumed in large quantity may cause confusion, drowsiness, blurred vision, tachycardia, nausea, vomiting, flushing, headache, dry mouth, diarrhea, and hyper motility. No specific antidote is known. Omeprazole is extensively protein bound and therefore is not readily dialyzable. In the event of overdosage, treatment should be symptomatic and supportive. gastric lavage may be useful

DOSAGE AND ADMINISTRATION
Adults : The usually recommended dose is one capsule of Enteric Coated Omeprazole and Domperidone SR Capsules once daily before meal.
Elderly : No dosage adjustment is required.
Pediatric use : Safety and efficacy have not been established.
Renal and hepatic impairment : No dosage adjustment is required in patients with renal and hepatic impairment.

STORAGE INSTRUCTIONS
Store below 25°C. Protect from light and moisture.

SHELF LIFE : 30 Months

PRODUCT SPECIFICATION : Manufacturer

PRESENTATION :
10 capsules in each strip

- 100 capsules (10 x 10's) in a box
- 30 capsules (3 x 10's) in a box

NOTE :

- Read the instruction thoroughly before use.
- Use upon doctor's prescription only.
- Please do not use the drug after expiry date.
- Please do not use the drug if there are any significant changes in appearance of the capsules.
- Keep out of reach of children.

I-L801-N19-00-01

MEGA
We care

Manufactured for :
MEGA LIFESCIENCES (AUSTRALIA) PTY LTD
Victoria 3810, Australia.

Manufactured by :
INVENTIA HEALTHCARE LTD.
F1-F1/1, Additional Ambernath M.I.D.C.,
Ambernath (East), Thane 421506, Maharashtra State, India.

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