ESOTOR
Esomeprazole

COMPOSITION
Esotor 20 Tablet: Each enteric coated tablet contains Esomeprazole Magnesium Trihydrate BP equivalent to Esomeprazole 20 mg.
Esotor 20 Capsule: Each capsule contains enteric coated pellets of Esomeprazole Magnesium Trihydrate BP equivalent to Esomeprazole 20 mg.
Esotor 40 Tablet: Each enteric coated tablet contains Esomeprazole Magnesium Trihydrate BP equivalent to Esomeprazole 40 mg.
Esotor 40 Capsule: Each capsule contains enteric coated pellets of Esomeprazole Magnesium Trihydrate BP equivalent to Esomeprazole 40 mg.
Esotor 40 IV Injection: Each vial contains sterile lyophilized cake or powder of Esomeprazole Sodium BP equivalent to Esomeprazole 40 mg and each ampoule contains 5 ml of 0.9% Sodium Chloride BP Injection.

PHARMACOLOGY
Esotor (Esomeprazole) is a proton pump inhibitor that suppresses gastric acid secretion by inhibition of the H^+/K^+-ATPase in the gastric parietal cell.

INDICATIONS
Tablet / Capsule: Healing of erosive esophagitis (EE) in adults and pediatric patients (12-17 years); Maintenance of healing of EE in adults; Treatment of heartburn and other symptoms associated GERD in adults and pediatric patients (12-17 years); Risk reduction of NSAID-associated gastric ulcer in adults at risk; *H. pylori* eradication to reduce the risk of duodenal ulcer recurrence (Triple Therapy); Treatment of pathological hypersecretory conditions, including Zollinger-Ellison syndrome in adults.
IV Injection/Infusion: Gastroesophageal Reflux Disease (GERD) with erosive esophagitis (EE) in adults and pediatric (1 month to 17 years), as an alternative to oral therapy; Risk reduction of rebleeding of gastric or duodenal ulcers following therapeutic endoscopy for acute bleeding gastric or duodenal ulcers in adults.

DOSAGE AND ADMINISTRATION
Tablet / Capsule
Healing of Erosive Esophagitis (EE): 20-40 mg once daily for 4-8 weeks. Consider an additional 4-8 weeks if required. For pediatric (12-17 years) patients, 20-40 mg once daily for 4-8 Weeks.
Maintenance dose of Healing of Erosive Esophagitis (EE): 20 mg once daily; Controlled studies do not extend beyond 6 months.
Treatment of Symptomatic GERD: 20 mg once daily for 4 weeks; Consider an additional 4 weeks if required. For pediatric (12-17 years) patients, 20 mg once daily for 4 Weeks.
Risk Reduction of NSAID-Associated Gastric Ulcer: 20-40 mg once daily; Controlled studies do not extend beyond 6 months. A maximum dosage of 20 mg once daily is recommended for patients with severe liver impairment (Child-Pugh Class C).
***H. pylori* Eradication to Reduce the Risk of Duodenal Ulcer Recurrence (Triple Therapy):** Esotor 40 mg once daily, Amoxicillin 1000 mg twice daily and Clarithromycin 500 mg twice daily for 10 days.
Pathological Hypersecretory Conditions including Zollinger-Ellison Syndrome: The starting dose is 40 mg twice daily; individualize the regimen to patient needs. Dosages of up to 240 mg/day can be administered.
IV Injection/Infusion:
GERD with Erosive Esophagitis: 20-40 mg once daily for adults by IV injection (no less than 3 minutes) or IV infusion (10-30 minutes) for up to 10 days. The maximum dosage for severe hepatic impaired patients, the dose is 20 mg once daily. For pediatric patients, daily dose is 0.5 mg/kg (1 month to <1 year) or 10 mg (1-17 years having body weight <55 kg) or 20 mg (1-17 years having body weight >55 kg) as IV infusion over 10-30 minutes for up to 10 days.
Risk Reduction of Rebleeding of Gastric and Duodenal Ulcers: 80 mg administered as an IV infusion over 30 minutes, followed by a continuous infusion of 8 mg/hour for 71.5 hours for severe hepatic impairment (Child-Pugh Class C), followed by continuous infusion dose is 4 mg/hour and for mild to moderate hepatic impairment (Child-Pugh Class A, B respectively), this dose will be 6 mg/hour.
IV therapy is aimed solely at the acute initial management of bleeding gastric or duodenal ulcers. Administer oral acid-suppressive therapy following IV therapy for a full course of treatment.
Preparation, Administration & Storage: For IV injection of 40 mg dose, reconstitute the content of a vial with 5 mL of 0.9% Sodium Chloride Injection and then withdraw this dose to use as IV injection over no less than 3 minutes. For IV infusion of 40 mg dose, reconstituted solution the one vial further diluted with 45 ml of 0.9% Sodium Chloride Injection or Lactated Ringer's Injection or 5% Dextrose Injection and then administer the dose as IV infusion over 10-30 minutes. For doses of 80 mg and above, proportional amount of vial content and diluent will be used.
Discard any unused portion of Esotor IV solution remaining in the vial. Inspect the reconstituted solution visually for particulate matter and discoloration prior to and during administration. Flush the IV line with either 0.9% Sodium Chloride Injection, Lactated Ringer's Injection, or 5% Dextrose Injection both prior to and after administration of Esotor IV.
Store the final (diluted) solution of Esotor IV at room temperature up to 30°C (86°F). Administer the solution diluted with 0.9% sodium chloride or Lactated Ringer's solution within 12 hours and with 5% Dextrose injection within 6 hours.

CONTRAINDICATION
It is contraindicated in patients with known hypersensitivity to any component of the formulation or substituted benzimidazoles.

WARNING AND PRECAUTION
Gastric Malignancy: Symptomatic response with Esotor does not preclude the presence of gastric malignancy. Consider additional follow-up and diagnostic testing.
Acute Tubulointerstitial Nephritis: Discontinue treatment and evaluate patients.
Clostridium difficile-Associated Diarrhea: PPI therapy may be associated with increased risk.
Bone Fracture: Long-term and multiple daily dose PPI therapy may be associated with an increased risk for osteoporosis-related fractures of the hip, wrist or spine.
Severe Cutaneous Adverse Reactions: Discontinue at the first signs or symptoms.
Cutaneous and Systemic Lupus Erythematosus: Discontinue Esotor and refer to a specialist for evaluation.
Cyanocobalamin (Vitamin B12) deficiency: Daily long-term use (longer than 3 years) may lead to malabsorption or a deficiency of Cyanocobalamin.
Hypomagnesemia and Mineral Metabolism: Reported rarely with prolonged treatment with PPIs.
Fundic Gland Polyps: Risk increases with long-term use, especially beyond one year. Use the shortest duration of therapy.
Interactions with Diagnostic Investigations for Neuroendocrine Tumors: Temporarily stop Esotor at least 14 days before assessing CGA levels.

SIDE EFFECT
The most common adverse reactions (>1%) are headache, diarrhea, nausea, flatulence, abdominal pain, constipation, dry mouth, somnolence, injection site reaction, dizziness/vertigo, and pruritus.

USE IN PREGNANCY AND LACTATION
There are no adequate and well-controlled studies with Esomeprazole in pregnant women. There is no clinical data on the use of Esomeprazole during breast-feeding.

USE IN CHILDREN AND ADOLESCENTS
Use is not recommended for the treatment of symptomatic GERD in patients 1 month to less than 1 year of age.

DRUG INTERACTION
Rilpivirine, Atazanavir and Nelfinavir: Concomitant use may reduce the antiviral effect and promote the development of drug resistance.
Saquinavir: Concomitant use may increase the toxicity.
Warfarin: Concomitant use may increase INR and prothrombin time.
Methotrexate: Concomitant use may elevate and prolong serum concentrations of Methotrexate and/or its metabolite.
Clopidogrel: Concomitant use resulted in reduced plasma concentrations of the active metabolite of Clopidogrel and a reduction in platelet inhibition.
Citalopram: Increased exposure of Citalopram leads to an increased risk of QT prolongation.
Cilostazol: Increased exposure of Cilostazol and one of its active metabolites.
Digoxin: Potential for increased exposure of Digoxin.
St. John's Wort and Rifampin: Decrease the Esomeprazole concentration.
Iron Salts, Erlotinib, Dasatinib, Nilotinib, Mycophenolate Mofetil, Ketoconazole / Itraconazole: Can reduce the absorption of these drugs due to its effect on reducing intragastric acidity.
Tacrolimus: Potentially increased exposure of Tacrolimus, especially in transplant patients who are intermediate or poor metabolizers of CYP2C19.

OVERDOSAGE
In the event of overdosage, treatment should be symptomatic and supportive.

STORAGE
Store below 30°C temperature in a cool and dry place. Protect from light and moisture. Keep out of the reach of children.

HOW SUPPLIED
Esotor 20 Tablet: Each box contains 50 tablets in Alu-Alu blister pack.
Esotor 20 Capsule: Each box contains 50 capsules in Alu-Alu blister pack.
Esotor 40 Tablet: Each box contains 30 tablets in Alu-Alu blister pack.
Esotor 40 Capsule: Each box contains 40 capsules in Alu-Alu blister pack.
Esotor 40 IV Injection: Each combipack contains one vial containing sterile lyophilized cake or powder of Esomeprazole Sodium BP equivalent to Esomeprazole 40 mg and one ampoule of 5 ml 0.9% Sodium Chloride BP Injection. It also contains a sterile disposable syringe (5 ml).

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NIPRO JMI Pharma

Manufactured by:
NIPRO JMI Pharma Ltd.
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