mep®-B

(Omeprazole / Sodium Bicarbonate)

Insta Sachet

20mg / 1680mg **40mg / 1680mg**

Powder For Oral Suspension

میپ۔ بی انسٹا

(اومیپرازول/سوڈیم بائیکاربونیٹ) ساشے

۲۰ ملی گرام/۱۶۸۰ ملی گرام ۴۰ ملی گرام/۱۶۸۰ ملی گرام

Mint Flavour

QUALITATIVE AND QUANTITATIVE COMPOSITION

mep®-B Insta Sachet 20mg/1680mg

Each sachet contains: Omeprazole U.S.P. 20mg

Sodium Bicarbonate U.S.P. ...1680mg, Innovator's Specification

mep®-B Insta Sachet 40mg/1680mg

Each sachet contains: Omeprazole U.S.P. 40mg

Sodium Bicarbonate U.S.P. ...1680mg, Innovator's Specification

DESCRIPTION:

mep®-B Insta (omeprazole/sodium bicarbonate) is a combination of omeprazole, a proton-pump inhibitor, and sodium bicarbonate, an antacid. Omeprazole is a substituted benzimidazole, 5-methoxy-2-[[(4-methoxy-3, 5-dimethyl-2-pyridinyl)methyl] sulfinyl]-1H-benzimidazole, a racemic mixture of two enantiomers that inhibits gastric acid secretion. Its empirical formula is C17H19N3O3S, with a molecular weight of 345.42.

CLINICAL PHARMACOLOGY:

Mechanism of Action: Omeprazole belongs to a class of antisecretory compounds, the substituted benzimidazoles, that do not exhibit anticholinergic or H2 histamine antagonistic properties, but that suppress gastric acid secretion by specific inhibition of the H+/K+ ATPase enzyme system at the secretory surface of the gastric parietal cell. **Pharmacokinetics: Absorption:** Following single or repeated once-daily dosing, peak plasma concentrations of omeprazole from mep®-B Insta are approximately proportional from 20 to 40 mg doses, but a greater than linear mean AUC (three-fold increase) is observed when doubling the dose to 40 mg. The bioavailability of omeprazole from mep®-B Insta increases upon repeated administration. When mep®-B Insta is administered 1 hour after a meal, the omeprazole AUC is reduced by approximately 24% relative to administration 1 hour prior to a meal. **Distribution:** Omeprazole is bound to plasma proteins. Protein binding is approximately 95%. **Metabolism:** Following single-dose oral administration of omeprazole, the majority of the dose (about 77%) is eliminated in urine as at least six metabolites. Two metabolites have been identified as hydroxyomeprazole and the corresponding carboxylic acid. The remainder of the dose was recoverable in feces. This implies a significant biliary excretion of the metabolites of omeprazole. Three metabolites have been identified in plasma – the sulfide and sulfone derivatives of omeprazole, and hydroxyomeprazole. These metabolites have very little or no antisecretory activity. **Elimination:** Following single-dose oral administration of omeprazole, little, if any, unchanged drug is excreted in urine. The mean plasma omeprazole half-life in healthy subjects is approximately 1 hour (range 0.4 to 3.2 hours), and the total body clearance is 500-600 mL/min.

PHARMACODYNAMICS:

Omeprazole has been characterized as a gastric acid pump inhibitor, in that it blocks the final step of acid production. This effect is dose related and leads to inhibition of both basal and stimulated acid secretion irrespective of the stimulus.

INDICATIONS AND USAGE:

Duodenal Ulcer: mep®-B Insta (omeprazole/sodium bicarbonate) is indicated for short-term treatment of active duodenal ulcer. Most patients heal within four weeks. Some patients may require an additional four weeks of therapy. **Gastric Ulcer:** It is indicated for short-term treatment (4¬8 weeks) of active benign gastric ulcer. **Treatment of Gastro-esophageal Reflux Disease (GERD):** Symptomatic GERD: Mep-B Insta is indicated for the treatment of heartburn and other symptoms associated with GERD for up to 4 weeks. **Erosive Esophagitis:** It is indicated for the short-term treatment (48 weeks) of erosive esophagitis which has been diagnosed by endoscopy. The efficacy of mep®-B Insta used for longer than 8 weeks in these patients has not been established. Maintenance of Healing of Erosive Esophagitis: It is indicated to maintain healing of erosive esophagitis. Reduction of Risk of Upper Gastrointestinal Bleeding in **Critically Ill Patients (40mg/1680mg oral suspension only):** mep®-B Insta Powder for Oral Suspension 40 mg/1680 mg is indicated for the reduction of risk of upper GI bleeding in critically ill patients. **Contraindications:** mep®-B Insta is contraindicated in patients with known hypersensitivity to any components of the formulation. Hypersensitivity reactions may include anaphylaxis, anaphylactic shock, angioedema, bronchospasm, acute interstitial nephritis, and urticarial.

INTERACTIONS:

DRUG INTERACTIONS:

Drugs for Which Gastric pH Can Affect Bioavailability: the absorption of drugs such as ketoconazole, atazanavir, iron salts, erlotinib, and mycophenolate mofetil (MMF) can decrease, while the absorption of drugs such as digoxin can increase during treatment with omeprazole.**Drugs Metabolized by Cytochrome P450 (CYP):** Omeprazole can prolong the elimination of diazepam, warfarin and phenytoin, drugs that are metabolized by oxidation in the liver. Patients treated with proton pump inhibitors and warfarin may need to be monitored for increases in INR and prothrombin time. Concomitant administration of omeprazole and voriconazole (a combined inhibitor of CYP2C19 and CYP3A4) resulted in more than doubling of the omeprazole exposure. Avoid concomitant use of St. John's wort or rifampin with omeprazole. **Antiretroviral Agents:** Concomitant administration of atazanavir and proton pump inhibitors is not recommended. Coadministration of atazanavir with proton pump inhibitors is expected to substantially decrease atazanavir plasma concentrations and thereby reduce its therapeutic effect. Concomitant administration with omeprazole and drugs such as atazanavir and nelfinavir is therefore not recommended. For other antiretroviral drugs, such as saquinavir, elevated serum levels have been reported with an increase in AUC. **Combination Therapy with Clarithromycin:** Concomitant administration of clarithromycin with other drugs can lead to serious adverse reactions due to drug interaction. **Clopidogrel:** Omeprazole is an inhibitor of CYP2C19 enzyme. Clopidogrel is metabolized to its active metabolite in part by CYP2C19. Concomitant use of omeprazole 80 mg results in reduced plasma concentrations of the active metabolite of clopidogrel and a reduction in platelet inhibition. **Tacrolimus:** Concomitant administration of omeprazole and tacrolimus may increase the serum levels of tacrolimus. **Interactions with Investigations of Neuroendocrine Tumors:** Drug induced decrease in gastric acidity results in enterochromaffin like cell hyperplasia and increased Chromogranin A levels which may interfere with investigations for neuroendocrine tumors. **Methotrexate:** concomitant administration of PPIs and methotrexate may elevate and prolong serum levels of methotrexate &/or its metabolite hydroxymethotrexate.

USE IN SPECIFIC POPULATION:

Pregnancy: Pregnancy Category C: mep®-B Insta should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. **Breast Feeding:** omeprazole is 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 to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother. In addition, sodium bicarbonate should be used with caution in nursing mothers. **Pediatric Use:** Safety and effectiveness of mep®-B Insta have not been established in pediatric patients less than 18 years of age. **Geriatric Use:** no dosage adjustment is necessary in the elderly.

Hepatic Impairment: Consider dose reduction, particularly for maintenance of healing of erosive esophagitis. **Renal Impairment:** No dose reduction is necessary. **Asian Population:** Recommend dose reduction, particularly for maintenance of healing of erosive esophagitis.

WARNINGS AND PRECAUTIONS

Presence of Gastric Malignancy: In adults, symptomatic response does not preclude the presence of gastric malignancy. Consider additional follow-up and diagnostic testing. **Acute Interstitial Nephritis:** Acute interstitial nephritis has been observed in patients taking PPIs. Discontinue mep®-B Insta if acute interstitial nephritis develops. **Buffer Content:** The sodium content of mep®-B Insta products should be taken into consideration when administering to patients on a sodium restricted diet. Because Mep-B Insta contain sodium bicarbonate, it should be used with caution in patients with Bartter's syndrome, hypokalemia, hypocalcemia, and problems with acid base balance. Long-term administration of bicarbonate with calcium or milk can cause milkalkali syndrome. Chronic use of sodium bicarbonate may lead to systemic alkalosis, and increased sodium intake can produce edema and weight increase. **Clostridium difficile¬Associated Diarrhea:** PPI therapy like mep®-B Insta may be associated with an increased risk of Clostridium difficile¬associated diarrhea, especially in hospitalized patients. Patients should use the lowest dose and shortest duration of PPI therapy appropriate to the condition being treated. **Bone Fracture:** proton pump inhibitor (PPI) therapy may be associated with an increased risk for osteoporosis related fractures of the hip, wrist, or spine. The risk of fracture was increased in patients who received high dose, defined as multiple daily doses, and long-term PPI therapy. Patients should use the lowest dose and short-est duration of PPI therapy appropriate to the condition being treated. **Cutaneous and Systemic Lupus Erythematosus:** Cutaneous lupus erythematosus (CLE) and systemic lupus erythe-matosus (SLE) have been reported in patients taking PPIs, including omeprazole. Systemic lupus erythematosus (SLE) is less commonly reported than CLE in patients receiving PPIs. Avoid administration of PPIs for longer than medically indicated. If signs or symptoms consistent with CLE or SLE are noted in patients receiving Mep B Insta, discontinue the drug. **Cyanocobalamin (Vitamin B¬12) Deficiency:** Daily treatment with any acid suppressing medications over a long period of time (e.g., longer than 3 years) may lead to malabsorption of cyanocobalamin (vitamin B¬12) caused by hypo¬ or achlorhydria. Hypomagnesemia Hypomagnesemia, symptomatic and asymptomatic, has been reported rarely in patients treat-ed with PPIs for at least three months, in most cases after a year of therapy. Serious adverse events include tetany, arrhythmias, and seizures. In most patients, treatment of hypomagnesemia required magnesium re-placement and discontinuation of the PPI. For patients expected to be on prolonged treatment or who take PPIs with medications such as digoxin or drugs that may cause hypomagnesemia (e.g., diuretics), healthcare profes-sionals may consider monitoring magnesium levels prior to initiation of PPI treatment and periodically. **Fundic Gland Polyps:** PPI use is associated with an increased risk of fundic gland polyps that increases with long-term use, especially beyond one year. Most PPIs users who developed fundic gland polyps were asymptomatic and fundic gland polyps were identified incidentally on endoscopy. Use the shortest duration of PPI therapy appropriate to the condition being treated.

IMPORTANT SAFETY INFORMATION:

MHRA ADVICE: PROTON PUMP INHIBITORS (PPIS): VERY LOW RISK OF SUBACUTE CUTANEOUS LUPUS ERYTHEMA-TOSUS (SEPTEMBER 2015) Very infrequent cases of subacute cutaneous lupus erythematosus (SCLE) have been reported in patients taking PPIs. Drug-induced SCLE can occur weeks, months or even years after exposure to the drug. If a patient treated with a PPI develops lesions-especially in sun-exposed areas of the skin—and it is accompanied by arthralgia: Advise them to avoid exposing the skin to sunlight; consider SCLE as a possible diagnosis; consider discontinuing PPI treatment unless it is imperative for a serious acid-related condition; a patient who develops SCLE with a particular PPI may be at risk of the same reaction with another; in most cases, symptoms resolve on PPI with-drawal; topical or systemic steroids might be necessary for treatment of SCLE only if there are no signs of remission after a few weeks or months.

DOSAGE AND ADMINISTRATION:

Since both the 20 mg and 40 mg oral suspension sachets contain the same amount of sodium bicarbonate (1,680 mg), two sachets of 20 mg are **not equivalent** to one packet of mep®-B Insta 40 mg. Instruct patients that Mep-B Insta should be taken on an empty stomach at least one hour prior to a meal. For patients receiving continuous Nasogastric (NG)/Orogastric (OG) tube feeding, before and 1 hour after administration of mep®-B Insta enteral feeding should be suspended approximately 3 hours Powder for Oral Suspension.

Recommended Doses of mep®-B Insta by Indication for Adults

18 Years and Older

Indication	Recommended Dose	Frequency
Short Term Treatment of Active Duodenal Ulcer	20 mg	Once daily for 4 weeks 1,2
Benign Gastric Ulcer	40 mg	Once daily for 4 8 weeks 2,3
Gastroesophageal Reflux Disease (GERD)		
Symptomatic GERD (with no esophageal erosions)	20 mg	Once daily for up to 4 weeks 2
Erosive Esophagitis	20 mg	Once daily for 4 8 weeks 2
Maintenance of Healing of Erosive Esophagitis	20 mg	Once daily 3
Reduction of Risk of Upper Gastrointestinal Bleeding in Critically Ill Patients (40 mg oral suspension only)	40 mg	40 mg initially followed by 40mg 68 hours later and 40 mg daily thereafter for 14 days 3

Preparation and Administration of Suspension: Directions for use: Empty packet contents into a small cup containing 1 - 2 tablespoons of water. DO NOT USE OTHER LIQUIDS OR FOODS. Stir well and drink immediately. Refill cup with water and drink. If Mep-B Insta is to be administered through a nasogastric (NG) or orogastric (OG) tube, the suspension should be constituted with approximately 20 mL of water. DO NOT USE OTHER LIQUIDS OR FOODS. Stir well and administer immediately. An appropriately-sized syringe should be used to instill the suspension in the tube. The suspension should be washed through the tube with 20 mL of water. **Overdosage:** Doses ranged up to 2400 mg included confusion, drowsiness, blurred vision, tachycardia, nausea, vomiting, diaphoresis, flushing, headache, dry mouth, and other adverse reactions similar to those seen in normal clinical experience No specific antidote for omeprazole overdosage is known. Omeprazole is extensively protein bound and is, therefore, not readily dialyzable. In the event of overdosage, treatment should be symptomatic and supportive. **Adverse Reactions:** Hypersensitivity Reactions, Acute Interstitial Nephritis, Clostridium difficile Associated Diarrhea, Bone Fracture, Cutaneous and Systemic Lupus Erythematosus, Cyanocobalamin (Vitamin B12) Deficiency, Hypomagnesemia.

DOSAGE:

As directed by the physician.

INSTRUCTIONS:

Store below 30°C. Protect from heat, light and moisture.
Keep all medicines out of the reach of children.

PRESENTATION:

mep®-B Insta Sachet (Omeprazole + Sodium bicarbonate) 20mg/1680mg Powder for oral suspension is available in pack of 10 sachets.
mep®-B Insta Sachet (Omeprazole + Sodium bicarbonate) 40mg/1680mg Powder for oral suspension is available in pack of 10 sachets.

علامات/طریقہ استعمال: میپ بی انسٹا ساشے معدے اور آنتوں کے السر اور سوزش، تیزابیت اور سینے کی جلن کے علاج کے لیے تجویز کردہ ہے۔
ساشے کے اجزا کو 1 سے 2 چمچے پانی میں حل کر کے فوراً استعمال کریں۔
مضر اثرات: حساسیت، گردوں میں ورم، ہڈی ٹوٹنا، وٹامن B12 کی کمی، خون میں میگنیشیم کی کمی۔
احتیاطی تدابیر: دودھ پلانے والی ماؤں اور حاملہ خواتین میں میپ بی انسٹا صرف مستند ڈاکٹر کی ہدایت پر استعمال کریں۔ جگر کے مریضوں میں دوا کا استعمال احتیاط سے کریں۔
خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
ہدایات: ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔ گرمی، روشنی اور نمی سے محفوظ رکھیں۔

For detailed information:

GENIX **Genix Pharma (Pvt.) Ltd.**

44,45-B, Korangi Creek Road, Karachi-75190, Pakistan.
UAN: +92-21-111-10-10-11, **Email:** info@genixpharma.com

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www.genixpharma.com