Sachet/Capsule

PROMIZ INSTA

(Omeprazole USP + Sodium bicarbonate BP)

پرومز انسٹا ساشے/کیپسول

(اومیپرازول۔یو ایس پی+سوڈیم بائیکاربونیٹ۔بی پی)

COMPOSITION:

Promiz Insta Sachet 20/1680mg

Each sachet contains:

Omeprazole (USP)……20mg

Sodium bicarbonate (BP)……1680mg

Promiz Insta Sachet 40/1680mg

Each sachet contains:

Omeprazole (USP)……40mg

Sodium bicarbonate (BP)……1680mg

Promiz Insta Capsule 20/1100mg

Each capsule contains:

Omeprazole (USP)……20mg

Sodium bicarbonate (BP)……1100mg

Promiz Insta Capsule 40/1100mg

Each capsule contains:

Omeprazole (USP)……40mg

Sodium bicarbonate (BP)……1100mg

Product complies Innovator's specs.

DESCRIPTION:

PROMIZ INSTA (Omeprazole + Sodium bicarbonate) is a combination of omeprazole, a proton-pump inhibitor and sodium bicarbonate, an antacid. PROMIZ INSTA contains immediate-release formulation of omeprazole and sodium bicarbonate. Sodium bicarbonate raises the gastric pH and thus protect omeprazole from acid degradation.

INDICATIONS:

Duodenal Ulcer

PROMIZ 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

PROMIZ INSTA is indicated for short-term treatment (4-8 weeks) of active benign gastric ulcer

Treatment of Gastroesophageal Reflux Disease (GERD)

Symptomatic GERD

PROMIZ INSTA is indicated for the treatment of heartburn and other symptoms associated with GERD.

Erosive Esophagitis

PROMIZ INSTA is indicated for the short-term treatment (4-8 weeks) of erosive esophagitis which has been diagnosed by endoscopy. The efficacy of PROMIZ INSTA used for longer than 8 weeks in these patients has not been established. If a patient does not respond to 8 weeks of treatment, it may be helpful to give up to an additional 4 weeks of treatment. If there is recurrence of erosive esophagitis or GERD symptoms (e.g., heartburn), additional 4-8 week courses of PROMIZ INSTA may be considered.

Maintenance of Healing of Erosive Esophagitis

PROMIZ INSTA is indicated to maintain healing of erosive esophagitis. Controlled studies do not extend beyond 12 months.

Reduction of Risk of Upper Gastrointestinal Bleeding in Critically ILL Patients (40mg oral suspension only)

PROMIZ INSTA Powder for Oral Suspension 40 mg/1680 mg is indicated for the reduction of risk of upper GI bleeding in critically ill patients.

MECHANISM OF ACTION:

Omeprazole reduces gastric acid secretion through a unique mechanism of action. Omeprazole belongs to a class of anti-secretory compounds - the substituted benzimidazoles that do not exhibit anti-cholinergic or H2 histamine antagonistic properties. It inhibits secretion of gastric acid by irreversibly blocking the enzyme system of hydrogen/potassium adenosine triphosphatase (H+/K+ATPase), the proton pump of the gastric parietal cell. This effect is dose-related and leads to inhibition of both basal and stimulated acid secretion irrespective of the stimulus.

DOSAGE & ADMINISTRATION:

PROMIZ INSTA (omeprazole/sodium bicarbonate) is available as a capsule and as a powder for oral suspension in 20 mg and 40 mg strengths of omeprazole for adult use.

All recommended doses throughout the labeling are based upon omeprazole Since both the 20 mg and 40 mg oral suspension packets contain the same amount of sodium bicarbonate (1680 mg), two packets of 20 mg are not equivalent to one packet of PROMIZ INSTA 40 mg; therefore, two 20 mg packets of PROMIZ INSTA should not be substituted for one packet of PROMIZ INSTA 40 mg.

Since both the 20 mg and 40 mg capsules contain the same amount of sodium bicarbonate (1100 mg), two capsules of 20 mg are not equivalent to one capsule of PROMIZ INSTA 40 mg; therefore, two 20 mg capsules of PROMIZ INSTA should not be substituted for one capsule of PROMIZ INSTA 40 mg. PROMIZ INSTA should be taken on an empty stomach at least one hour before a meal.

For patients receiving continuous Nasogastric (NG)/ Orogastric (OG) tube feeding, enteral feeding should be suspended approximately 3 hours before and 1 hour after administration of PROMIZ INSTA Powder for Oral Suspension.

Indication	Recommended Dose	Frequency
Short-Term Treatment of Active Duodenal Ulcer	20 mg	Once daily for 4 weeks
Benign Gastric Ulcer	40 mg	Once daily for 4-8 weeks
Gastroesophageal Reflux Disease (GERD)		
a) Symptomatic GERD (with no esophageal erosions)	20 mg	Once daily for up to 4 weeks
b) Erosive Esophagitis	20 mg	Once daily for 4-8 weeks
Maintenance of Healing of Erosive Esophagitis	20 mg	Once daily
Reduction of Risk of Upper Gastrointestinal Bleeding in Critically Ill Patients (40 mg oral suspension only)	40 mg	40 mg initially followed by 40 mg 6-8 hours later and 40 mg daily thereafter for 14 days

Administration of Capsules

PROMIZ INSTA Capsules should be swallowed intact with water. DO NOT USE OTHER LIQUIDS. DO NOT OPEN CAPSULE AND SPRINKLE CONTENTS INTO FOOD.

Preparation and Administration of Suspension

Directions for use: Empty the sachet contents into a glass containing 15-30 ml water (1-2 tablespoons).Stir well and drink immediately. Refill the glass with water and drink. Do not use carbonated water, food or other liquids.

If PROMIZ 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.

PHARMACOKINETICS:

Absorption:

Omeprazole is acid-labile and is administered orally on an empty stomach 1 hour prior to a meal. The absorption of omeprazole is rapid, with mean peak plasma levels being 1954ng/mL (33%) occurring at about 30 minutes (range 10 to 90 minutes) after a single dose or repeated-dose administration. Absolute bioavailability of omeprazole powder for oral suspension is about 30-40% at doses 20-40mg due in large part to presystemic metabolism. When powder for oral suspension is administered 1 hour after a meal, the omeprazole AUC is reduced by approximately 24% relative to administered 1 hour prior to meal.

Distribution:

Omeprazole is bound to plasma proteins. Protein binding is approximately 95%.

Metabolism/ Excretion:

Following absorption, omeprazole is almost completely metabolized in the liver, primarily by the cytochrome P450 isoenzyme CYP2C19 to form hydroxy-omeprazole and to a small extent by CYP3A4 to form omeprazole sulfone. These metabolites are inactive and excreted mostly in the urine and to a lesser extent in the bile. The majority of the dose (77%) was eliminated in the urine. The remainder of the dose was recoverable in the feces. The mean plasma omeprazole half-life is approximately 1 hour (ranging from 0.4 to 3.2 hours) and the total body clearance is 500-600mL/min.

PRECAUTIONS:

Concomitant Gastric Malignancy

Symptomatic response to therapy with omeprazole does not preclude the presence of gastric malignancy.

Atrophic gastritis

Atrophic gastritis has been noted occasionally in gastric corpus biopsies from patients treated long-term with omeprazole.

Buffer Content

Each PROMIZ INSTA capsule contains 1100 mg (13 mEq) of sodium bicarbonate. The total content of sodium in each capsule is 304 mg. Each packet of PROMIZ INSTA Powder for Oral Suspension contains 1680 mg (20 mEq) of sodium bicarbonate (equivalent to 460 mg of Na+). The sodium content of PROMIZ INSTA products should be taken into consideration when administering to patients on a sodium restricted diet. Because PROMIZ INSTA products contain sodium bicarbonate, they 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 milk-alkali syndrome. Chronic use of sodium bicarbonate may lead to systemic alkalosis and increased sodium intake can produce edema and weight increase.

Pregnancy

Pregnancy Category C

There are no adequate and well controlled studies on the use of omeprazole in pregnant women. Omeprazole should be used during pregnancy only if the potential benefit to pregnant women justifies the potential risk to the fetus.

Nursing Mothers:

Omeprazole is excreted in human milk. Because of the potential for serious adverse reactions in nursing infants from omeprazole; 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. In addition, sodium bicarbonate should be used with caution in nursing mothers.

DRUG INTERACTIONS:

- Omeprazole can prolong the elimination of diazepam, warfarin and phenytoin, drugs that are metabolized by oxidation in the liver. There have been reports of increased INR and prothrombin time in patients receiving proton pump inhibitors, including omeprazole, and warfarin concomitantly. Increases in INR and prothrombin time may lead to abnormal bleeding and even death. Patients treated with proton pump inhibitors and warfarin may need to be monitored for increases in INR and prothrombin time. Although in normal subjects no interaction with theophylline or propranolol was found, there have been clinical reports of interaction with other drugs metabolized via the cytochrome P-450 system (e.g., cyclosporine, disulfiram, and benzodiazepines). Patients should be monitored to determine if it Is necessary to adjust the dosage of these drugs when taken concomitantly with omeprazole.
- Because of its profound and long-lasting inhibition of gastric acid secretion, it is theoretically possible that omeprazole may interfere with absorption of drugs where gastric pH is an important determinant of their bioavailability (e.g., ketoconazole, ampicillin esters, and iron salts).
- Concomitant administration of omeprazole and atazanavir has been reported to reduce the plasma levels of atazanavir.
- Concomitant administration of omeprazole and tacrolimus may increase the serum levels of tacrolimus.
- Co-administration of omeprazole and clarithromycin have resulted in increased plasma levels of omeprazole, clarithromycin, and 14-hydroxy-clarithromycin

SIDE EFFECTS:

Body as a Whole

Allergic reactions, including, rarely anaphylaxis, fever, pain, fatigue, malaise and abdominal swelling.

Cardiovascular

Chest pain or angina, tachycardia, bradycardia, palpitation, elevated blood pressure, and peripheral edema.

Gastrointestinal

Pancreatitis (sometimes fatal), anorexia, irritable colon, flatulence, fecal discoloration, esophageal candidiasis, mucosal atrophy of the tongue, dry mouth and stomatitis. During treatment with omeprazole, gastric fundic gland polyps have been noted rarely. These polyps are benign and appear to be reversible when treatment is discontinued.

Hepatic

Mild and, rarely, marked elevations of liver function tests [ALT (SGPT), AST (SGOT), gamma-glutamyl transpeptidase, alkaline phosphatase, and bilirubin (jaundice)]. In rare instances, overt liver disease has occurred, including hepatocellular, cholestatic, or mixed hepatitis, liver necrosis (sometimes fatal), hepatic failure (sometimes fatal), and hepatic encephalopathy.

Metabolic/Nutritional

Hyponatremia, hypoglycemia and weight gain.

Musculoskeletal

Muscle cramps, myalgia, muscle weakness, joint pain, and leg pain.

Nervous System/Psychiatric

Psychic disturbances including depression, agitation, aggression, hallucinations, confusion, insomnia, nervousness, tremors, apathy, somnolence, anxiety, dream abnormalities, vertigo, paresthesia and hemifacial dysesthesia.

Respiratory

Epistaxis and pharyngeal pain.

Skin

Rash and rarely, cases of severe generalized skin reactions including toxic epidermal necrolysis (TEN; sometimes fatal), Stevens-Johnson syndrome, and erythema multiforme (some severe); purpura and/or petechiae (sometimes with rechallenge); skin inflammation, urticaria, angioedema, pruritus, photosensitivity, alopecia, dry skin and hyperhydrosis.

Special Senses

Tinnitus and taste perversion.

Ocular

Blurred vision, ocular irritation, dry eye syndrome, optic atrophy, anterior ischemic optic neuropathy, optic neuritis and double vision.

Urogenital

Interstitial nephritis (sometimes with positive rechallenge), urinary tract infection, microscopic pyuria, urinary frequency, elevated serum creatinine, proteinuria, hematuria, glycosuria, testicular pain, and gynecomastia.

Hematologic

Rare instances of pancytopenia, agranulocytosis (sometimes fatal), thrombocytopenia, neutropenia, leukopenia, anemia, leukocytosis and hemolytic anemia have been reported. Additional adverse reactions that could be caused by sodium bicarbonate, include metabolic alkalosis, seizures and tetany.

CONTRAINDICATIONS:

PROMIZ INSTA is contraindicated in patients with known hypersensitivity to any components of the formulation. Hypersensitivity reactions may include anaphylaxis, anaphylactic shock, angioedema, bronchospasm, interstitial nephritis, and urticaria.

STORAGE & INSTRUCTIONS:

Store between 15-25°C.

Protect from heat, sunlight and moisture.

Keep away from the reach of children.

To be sold on the prescription of a registered medical practitioner only.

HOW SUPPLIED:

Promiz Insta Sachet 20/1680mg

10 sachets.

Promiz Insta Sachet 40/1680mg

10 sachets.

Promiz Insta Capsule 20/1100mg

14 capsules.

Promiz Insta Capsule 40/1100mg

14 capsules.

خوراک وطریقہ استعمال:

ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات:

دوا کو ۱۵-۲۵ ڈگری سینٹی گریڈ درجہ حرارت کے درمیان رکھیں۔

دھوپ گرمی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔

صرف رجسٹرڈ ڈاکٹر کے نسخے کے مطابق فروخت کریں۔

Manufactured by:

PHARMASOL

PRIVATE LIMITED

Plot # 549,Sundar Industrial Estate,

Lahore, Pakistan.