Promep Sachet

پرومیپ ۲۰، ۴۰ ملی گرام ساشے

[Omeprazole + Sodium Bicarbonate]
20mg +1680mg
&
40mg +1680mg
Powder for Oral Suspension

DESCRIPTION:

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

QUALITATIVE & QUANTITATIVE COMPOSITION:

PROMEP powder for oral suspension is available for oral administration as:
PROMEP Powder for Oral Suspension 20mg
Each sachet contains:
Omeprazole USP.....20mg
Sodium Bicarbonate USP...1680mg
(as buffer)
(Product Specs.: Sigma)
PROMEP Powder for Oral Suspension 40mg
Each sachet contains:
Omeprazole USP.....40mg
Sodium Bicarbonate USP...1680mg
(as buffer)
(Product Specs.: Sigma)

CLINICAL PHARMACOLOGY:

Mechanism of Action:
Omeprazole belongs to a class of anti-secretory compounds. 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.

Pharmacokinetics:
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 reaches at about 30 minutes. Omeprazole is 95% bound to plasma proteins.
Omeprazole is almost completely metabolized in the liver, primarily by the cytochrome P450 isoenzyme CYP2C19 and to a small extent by CYP3A4 to form inactive metabolites which are 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 remaining was recovered in feces. The plasma half -life of omeprazole is approximately 1 hour.

Special Population:

Geriatric:
The elimination rate of omeprazole was somewhat decreased in the elderly, and bioavailability was increased.

Renal Insufficiency:
No dose reduction is necessary in patients with renal impairment.

Hepatic Insufficiency:
Dose reduction, particularly where maintenance of healing of erosive esophagitis is indicated, for the hepatically impaired should be considered.

THERAPEUTIC INDICATIONS:

PROMEP powder for oral suspension is indicated:
1-The treatment of Gastro - Esophageal Reflux Disease (GERD):
-Treatment of heart burn and other symptoms associated with GERD
-Treatment of erosive esophagitis which has been diagnosed by endoscopy.
2-Short term treatment of active duodenal ulcer
3-Short term treatment of active benign gastric ulcer
4-For maintenance treatment of healing of erosive esophagitis
5-For reduction treatment of risk of upper GI bleeding in critically ill patients

DOSAGE & ADMINISTRATION:

Since both the 20 mg and 40 mg oral suspension sachets contain the same amount of sodium bicarbonate (1680 mg), two sachets of 20 mg are not equivalent to one packet of **PROMEP** 40 mg; therefore, two 20 mg sachets of **PROMEP** should not be substituted for one packet of **PROMEP** 40 mg.
PROMEP should be taken on an empty stomach at least one hour before a meal.

Recommended doses for Adults (18years & older)

Indications	Recommended Dose	Frequency
Short term treatment of active duodenal ulcer	20mg	Once daily for 4 weeks
Benign gastric ulcer	40mg	Once daily for 4-8 weeks
Reduction of risk of upper gastrointestinal bleeding in critically ill patients (40mg oral suspension only)	40mg	40mg initially followed by 40mg 6-8 hours later and 40mg daily thereafter for 14 days*
Gastroesophageal Reflux Disease (GERD)		
Symptomatic GERD (with no esophageal erosions)	20mg	Once daily for up to 4 weeks
Erosive esophagitis	20mg	Once daily for 4-8 weeks**
Maintenance of healing of erosive esophagitis	20mg	Once daily

*Most patients heal within 4 weeks. Some patients may require an additional 4 weeks of therapy.
The efficacy of **PROMEP Sachet used for longer than 8 weeks in these patients has not been established. In the rare instance of a patient not responding to 8 weeks of treatment, it may be helpful to give upto 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 omeprazole may be considered.

DIRECTIONS FOR USE:
-Empty the sachet content into 1 to 2 tablespoons (15mL-30mL) of water to form suspension.
-Stir well and drink immediately.
-Refill cup with water and drink.
-Do not use other liquids or foods.

CONTRAINDICATIONS:
- **PROMEP** is contraindicated in patients with known hypersensitivity to any component of the formulation.
-Sodium bicarbonate is contraindicated in patients with metabolic alkalosis and hypocalcemia.

PRECAUTIONS:
-Symptomatic response to therapy with omeprazole does not preclude the presence of gastric malignancy
-Atrophic gastritis has been noted occasionally in gastric corpus biopsies from patients treated long-term with omeprazole
-Sodium bicarbonate should be used with caution in patients with Bartter's syndrome, hypokalemia, respiratory alkalosis, and problems with acid-base balance.
-Long- term administration of bicarbonate with calcium or milk can cause milk-alkali syndrome.

Pregnancy:
PROMEP should be used during pregnancy only if the potential benefit to pregnant women justifies the potential risk to the fetus.

Nursing Mothers:
PROMEP Sachet is contraindicated in nursing mothers. In addition, sodium bicarbonate should be used with caution in nursing mothers.

DRUG INTERACTIONS:
-Omeprazole can prolong the elimination of diazepam, warfarin and phenytoin. Inhibition in elimination of warfarin, may lead to abnormal bleeding and even death. So monitoring of patient for increases in INR and prothrombin time taken into account
- Co- administration with atazanavir, reduces atazanavir plasma levels.
- Co-administration with tacrolimus, increases tacrolimus serum levels.
- Co-administration with clarithromycin resulted in increase plasma levels of omeprazole, clarithromycin, and 14-hydroxy-clarithromycin.

ADVERSE EFFECTS:

Body as a Whole:
Allergic reactions, fever, pain, fatigue and malaise.

Cardiovascular:
Chest pain, tachycardia, bradycardia, palpitation and hypertension.

Gastrointestinal:
Pancreatitis, anorexia, flatulence, fecal discoloration, mucosal atrophy of the tongue, dry mouth, stomatitis.

Hepatic:
Mild elevations of liver enzymes, rarely overt liver disease has occurred, including cholestatic, or mixed hepatitis, liver necrosis, hepatic failure, and hepatic encephalopathy.

Metabolic:
Hyponatremia, hypoglycemia, and weight gain.

Musculoskeletal:
Muscle cramps, muscle weakness & pain, joint pain, bone fracture and leg pain.

Nervous System:
Depression, agitation, aggression, hallucinations, insomnia, dream abnormalities, vertigo and hemifacial dysesthesia.

Respiratory:
Epistaxis, pharyngeal pain.

Skin:
Rash and rarely, cases of severe generalized skin reactions including toxic epidermal necrolysis, purpura and/or petechiae, skin inflammation, urticaria, angioedema, pruritus, photosensitivity, alopecia, dry skin, and hyperhidrosis.

Special Senses:
Tinnitus, taste perversion

Ocular:
Blurred vision, ocular irritation, dry eye syndrome, optic atrophy, optic neuritis and double vision.

Urogenital:
Interstitial nephritis, UTI, elevated serum creatinine, proteinuria, hematuria, glycosuria, testicular pain and gynecomastia.

Hematologic:
Rare instances of pancytopenia, agranulocytosis,thrombocytopenia, neutropenia, leukopenia, anemia, leukocytosis, and hemolytic anemia have been reported.
Additional adverse reactions related to sodium bicarbonate, include metabolic alkalosis, seizures and tetany.

OVERDOSAGE:
No specific antidote for omeprazole overdosage is known. In the event of overdosage treatment should be symptomatic and supportive.

INSTRUCTIONS:
-Store below 30°C
-Protect from light & moisture
-Keep out of reach of children

To be sold on prescription of a registered medical practitioner.

HOW SUPPLIED:
PROMEP (Omeprazole + Sodium bicarbonate) 20mg powder for oral suspension is available in packs of 10's.
PROMEP (Omeprazole + Sodium bicarbonate) 40mg powder for oral suspension is available in packs of 10's.

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔
ہدایت: دوا کو ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
روشنی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔
صرف رجسٹرڈ ڈاکٹر کے نسخے کے مطابق فروخت کریں۔

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