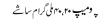
Promep Sachet



PROMEP powder for oral suspension is avail **PROMEP** Powder for Oral Suspension 20mg Each sachet contains:

Omeprazole USP......20mg Sodium Bicarbonate USP...1680mg

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

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.

2-Short term treatment of active doudenal ulcer
3-Short term treatment of active dening 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
blicarbonate (1880 mg), two sachets of 20 mg are not equivalent to one packet of #POMEP 40 mg;
PROMEP should be taken on an empty stomach at least one hour before a meal.
Recommended dose for Adults (1980-rat & older)

Recommended doses for Adults (18years & older	1)	
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 patier		

DIRECTIONS FOR USE:

E-mpty the sachet content into 1 to 2 tablespoons (15mL-30mL) of water to form suspension.

Set well and drink immediately.

Set well and soft immediately.

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CONTRAINDICTIONS or foods.

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**PROMETRY CONTRAINDICTI

m bicarbonate is contraindicated in patients with metabolic alkalosis and hypocalcemia.

PRECAUTIONS:
-Symptomatic response to therapy with omeprazole does not preclude the presence of gastric

-Atrophic gastritis has been noted occasionally in gastric corpus biopsies from patients treated long-

remojning gastitus inside user in the discussionally in gastitude purpose to open annual patients related unge - 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.

-Long-term administration of bicarbonate with calcium or milk can cause milk-alkali syndrome. Prognancy:
PROMEP should be used during pregnancy only if the potential benefit to pregnant women justifies the potential risk to the fetus.
Nursing Mothers:
WOMEP Sachet is contraindicated in nursing mothers. In addition, sodium bicarbonate should be

PROMER Sachet is contraindicated in nursing mothers. In addition, sodium bicarbonate should be used with caution in nursing mothers. In succession of many processions are considered to the contraint of wardarin, may lead to abnormal bileeding and even death. So monitoring of patient for increases in IMM and prothrombins time taken into account a level.

- Co-administration with attraints, reduces atzamative plasma levels.
- Co-administration with darkforency consult accommand levels.

clarithromycin, and 14-hydroxy-clarithromycin.
ADVERSE EFECTS.
Body as a Whole:
Allergic reactions, fever, pain, fatigue and malaise.
Cardiovascular:
Chest pain, tachycardia, bradycardia, palpitation and hypertension.
Gastrointestinal:
Pancreatits, anorexia, flatulence, fecal discoloration, mucosal atrophy of the tongue, dry mouth,

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

Ietabolic: Ayponatremia, hypoglycemia, and weight gain.

Hyponatremia, hypoglycemia, and weight gain.

Musculoskelteal:

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

Nervous System.

Depression, agitation, aggression, hallucinations, insomnia, dream abnormalities, vertigo and hemilicial dysethesia.

Respiratory:

Eleptaxis, phanyngeal pain.

Shir
Rash and rarely, cases of severe generalized skin reactions including toxic epidermal necrolysis,
purpura and/or petechiae, skin inflammation, urticaria, angloedema, 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.

Linematiza

Blurred vision, ocular irritation, dry eye syndrome, optic atrophy, optic neuritis and double vision. Urogenital:
Interstital 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.
OVENDOSACE:
OVEN

Manufactured by:
SIGMA PHARMA International (Pvt.) Ltd.

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