SPMC
OMEPRAZOLE GASTRO-RESISTANT CAPSULES IP 20 mg

PRESENTATION:
Omeprazole Gastro-resistant Capsules IP 20 mg:
Packs size- *500'S capsules bulk & Blisters containing 100'S capsules. (10x10)*

Light pink body & peach cap, size no.2 capsules printed with SPMC logo on the cap & "SPMC" letters on the body. Each capsule consists of enteric coated pellets of Omeprazole 20mg.

ACTION:
Proton pump inhibitors inhibit gastric acid secretion by blocking the hydrogen-potassium adenosine triphosphates enzyme system (the 'proton pump') of the gastric parietal cell.

INDICATION AND DOSE:
Helicobacter pylori eradication
in combination with Amoxicillin and clarithromycin; or in combination with Amoxicillin and metronidazole; or in combination with Clarithromycin and metronidazole
Adult**:** 20 mg twice daily
Eradication failure of Helicobacter pylori infection in Combination with Tripotassium dicitrato bismuthate, Tetracycline and metronidazole
Adult: 20 mg twice daily
Benign gastric ulceration
Adult: 20 mg once daily for 8 weeks, increased if Necessary to 40 mg once daily, in severe or recurrent cases
Duodenal ulceration
Adult: 20 mg once daily for 4 weeks, increased if Necessary to 40 mg once daily, in severe or recurrent cases
Prevention of relapse in gastric ulcer
Adult: 20 mg once daily, increased if necessary, to 40 mg once daily
Prevention of relapse in duodenal ulcer
Adult: 20 mg once daily, dose may range between 10–40 mg daily
NSAID-associated duodenal ulcer / NSAID-associated Gastric ulcer / NSAID-associated gastro duodenal erosions
Adult: 20 mg once daily for 4 weeks, continued for a Further 4 weeks if not fully healed
Prophylaxis in patients with a history of NSAID-associated Duodenal ulcer who require continued NSAID treatment | Prophylaxis in patients with a history of NSAID associated Gastric ulcer who require continued NSAID Treatment Prophylaxis in patients with a history of NSAID-associated gastro duodenal lesions who require Continued NSAID treatment Prophylaxis in patients with a history of NSAID-associated dyspeptic symptoms who Require continued NSAID treatment.
Adult: 20 mg once daily
Zollinger–Ellison syndrome
Adult: Initially 60 mg once daily; usual dose 20–120 mg Daily, total daily doses greater than 80mg should be given in 2 divided doses
Gastro-esophageal reflux disease
Adult: 20 mg once daily for 4 weeks, continued for a Further 4–8 weeks if not fully healed; maintenance 20 mg once daily
Gastro-Oesophageal reflux disease refractory to other treatment
Adult: 40 mg once daily for 8 weeks; maintenance 20 mg once daily.
Severe Oesophagitis
Adult: 40 mg once daily for 8 weeks, continue as maintenance treatment if appropriate
Acid reflux disease (long-term management)
Adult: 10 mg once daily, increased to 20 mg once daily, Dose only increased if symptoms return
Functional dyspepsia
Adult: 10 mg once daily for 4 weeks
Uninvestigated dyspepsia
Adult: 20 mg once daily for 4 weeks

CONTRA INDICATIONS:
Clostridium difficile infection. Inadequate Vitamin B_{12}. Low amount of magnesium in the blood, Liver problems, and Interstitial Nephritis. Sub-acute cutaneous lupus erythematosus. Systemic Lupus Erythematosus. Osteoporosis. Broken Bone, CYP2C19 poor metabolizer.

CAUTIONS:
Can increase the risk of fractures (particularly when used at high doses for over a year in the elderly) (in adults). May increase the risk of gastro-intestinal infections (including Clostridium difficile infection). May mask the symptoms of gastric cancer (in adults). Patients at risk of osteoporosis

SIDE EFFECTS:
Rare or very rare Aggression . agitation . bronchospasm . encephalopathy . gastrointestinal candidiasis . muscle weakness.
Significant: Hypomagnasaemia, cutaneous lupus erythematosus, SLE, osteoporosis-related fractures, fundic gland polyp, carcinoma, Clostridium difficile-associated diarrhoea, interstitial nephritis, Vitamin B_{12} deficiency (long-term therapy), gastrointestinal infection (e.g. salmonella, Campylobacter).
Gastrointestinal disorders: Nausea, vomiting, diarrhoea, constipation, flatulence, abdominal pain.
General disorders and administration site conditions: Weakness, malaise. *Hepatobiliary disorders:* Increased liver enzymes.
Immune system disorders: Urticaria.
Metabolism and nutrition disorders: Peripheral oedema.
Musculoskeletal and connective tissue disorders: Back pain.
Nervous system disorders: Headache, dizziness, somnolence, paraesthesia, vertigo.
Psychiatric disorders: Insomnia.
Respiratory, thoracic and mediastinal disorders: Cough.
Skin and subcutaneous tissue disorders: Rash, dermatitis, pruritus.

SPECIAL PRECAUTIONS:
Patient with reduced body store or risk factors for reduced vitamin B_{12} absorption; risk of osteoporosis. Hepatic impairment. Children, elderly. Pregnancy and lactation. CYP2C19 ultrarapid metabolisers.

PATIENT AND CARER ADVICE:
With oral use counselling on administration advised.

MONITORING PARAMETERS:
Rule out gastric malignancy prior to initiation of treatment. Monitor Mg concentrations prior to initiation and periodically thereafter.

USE IN PREGNANCY:
Not known to be harmful.

BREAST FEEDING:
Present in milk but not known to be harmful.

HEPATIC IMPAIRMENT:
Dose adjustments: Not more than 20 mg daily should be needed.

INTERACTION:
Do not take Omeprazole capsules if you are taking a medicine containing **nelfinavir** (used to treat HIV infection).

ADMINISTRATION:
Delayed-Release Cap: Should be taken on an empty stomach. Take at least 1 hour before meals. Swallow whole, do not chew/crush. For patients with difficulty swallowing, cap may be carefully opened & entire contents sprinkled in a spoonful of applesauce.

OVERDOSAGE:
Symptoms: nausea, vomiting, dizziness, abdominal pain, diarrhoea, headache apathy, depression and confusion.
Management: symptomatic and supportive treatment.

STORAGE:
Keep tightly closed in a cool dry place in original container. Protect from light. Store below 30^0 C.
Keep all medicines away from children

Manufactured by:
State Pharmaceuticals Manufacturing Corporation
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