SPMC
CO-TRIMOXAZOLE TABLETS BP

PRESENTATION:

Co-Trimoxazole Tablets BP, packs of 1000 Tablets

Each white, circular double convex tablets of 11.0 mm diameter with "SPC" or "SPMC" letters on one side and score mark on the reverse contains Sulfamethoxazole BP 400 mg and Trimethoprim BP 80 mg.

DRUG ACTION:
Sulfamethoxazole and trimethoprim are Used in combination (as co-trimoxazole) because of their Synergistic activity (the importance of the sulfonamides has decreased as a result of increasing bacterial resistance and their replacement by antibacterials which are Generally more active and less toxic).

INDICATIONS AND DOSE:
Treatment of susceptible infections
Child 6 weeks–5 months: 120 mg twice daily, Alternatively 24 mg/kg twice daily Child 6 months–5 years: 240 mg twice daily, alternatively 24 mg/kg twice daily Child 6–11 years: 480 mg twice daily, alternatively 24 mg/kg twice daily Child 12–17 years: 960 mg twice daily
Adult: 960 mg twice daily
Treatment of Pneumocystis jirovecii (Pneumocystis carinii) infections (undertaken where facilities for appropriate monitoring available—consult Microbiologist and product literature)
Child: 120 mg/kg daily in 2–4 divided doses for 14–21 days, oral route preferred for children
Adult: 120 mg/kg daily in 2–4 divided doses for 14–21 days.
Acute exacerbation of chronic obstructive pulmonary disease
Adult: 960 mg twice daily for 5 days
Prophylaxis of Pneumocystis jirovecii (Pneumocystis carinii) infections
Child: 450 mg/m2 twice daily (max. per dose 960 mg twice daily) for 3 days of the week (either consecutively or on alternate days), dose regimens may vary, consult local guidelines
Adult: 960 mg once daily, reduced if not tolerated to 480 mg once daily, alternatively 960 mg once daily on alternate days, alternate day dose to be given 3 times weekly, alternatively 960 mg twice a day on alternate days, alternate day dose to be given 3 times weekly

DOSE EQUIVALENCE AND CONVERSION:
480 mg of co-trimoxazole consists of sulfamethoxazole 400 mg and trimethoprim 80 mg

CAUTIONS:
Asthma. Avoid in blood disorders (unless under specialist supervision). Avoid in infants under 6 weeks (except for treatment or prophylaxis of pneumocystis pneumonia) because of the risk of kernicterus. Elderly (increased risk of serious side-effects). G6PD deficiency (risk of haemolytic anaemia). Maintain adequate fluid intake. Predisposition to folate deficiency. Predisposition to hyperkalaemia (in adults

RENAL IMPAIRMENT:
In adults Use half normal dose if eGFR 15–30 mL/minute/1.73m2. Avoid if eGFR less than 15 mL/minute/1.73m2 and if plasma-sulfamethoxazole Concentration cannot be monitored.
In children Use half normal dose if estimated glomerular filtration rate 15–30 mL/minute/1.73m2. Avoid if estimated glomerular filtration rate less than 15 mL/minute/1.73m2 and if plasma-sulfamethoxazole concentration cannot be monitored.

HEPATIC IMPAIRMENT
Avoid in severe liver disease.

MONITORING-REQUIREMENTS:
Monitor blood counts on prolonged treatment. In children Plasma concentration monitoring may be required with high doses; seek expert advice.

CONTRAINDICATIONS:
Acute porphyrias

SIDE EFFECTS:
Diarrhoea. Headache hyperkaliemia. Nausea. Rash Agranulocytosis. Bone marrow depression Anorexia. Antibiotic-associated colitis. Arthralgia. Aseptic meningitis. Ataxia. Blood disorders. Convulsions. Cough. Depression. Eosinophilia. Glossitis. Hallucinations. Hepatic necrosis. hypoglycaemia hyponatraemia . Interstitial nephritis. Jaundice. Leucopenia. Liver damage. Megaloblastic anaemia Myalgia. Myocarditis. Pancreatitis. Peripheral neuropathy Photosensitivity. Pulmonary infiltrates. Renal disorders. Shortness of breath. Stevens-Johnson syndrome. Stomatitis. Systemic lupus erythematosus. Thrombocytopenia. Tinnitus. Toxic epidermal necrolysis. Uveitis. Vasculitis. Vertigo

PRECAUTIONS:
Increased fluid intake is recommended. In case of high dose therapy, serum concentration should be monitered and folate supplementation should be considered. Caution must be observed in patients with renal impairment, elderly and during breast-feeding. Reduced dose may be necessary for patients with impaired renal functions depending on the creatinine clearence value.
Discontinue immediately if blood disorders or rash develops. Practice caution in patients with G6PD deficiency or with asthma. Avoid in infants under 6 weeks (except for treatment or prophylaxis of pneumocystis pneumonia.)

PREGNANCY:
Teratogenic risk in first trimester (Trimethoprim a folate antagonist). Neonatal haemolysis and methaemoglobinaemia in third trimester; fear of Increased risk of kernicterus in neonates appears to be Unfounded.

BREAST FEEDING:
Small risk of kernicterus in jaundiced infants and of haemolysis in G6PD-deficient infants (due to sulfamethoxazole).

DRUG INTERACTIONS:
Co-Trimoxazole may increase anti-coagulant effect of Warfarin, accumulation of Phenotoin in the body and the blood sugar lowering effect of oral anti-diabetic drugs.

STORAGE:
Keep tightly closed in a dry place at a temperature not exceeding 30^0C. Keep all medicines away from the reach of children. Keep in an airtight container.

Manufactured by
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Sri Lanka.