SPMC

Clarithromycin Tablets USP 250mg
Clarithromycin Tablets USP 500mg

PRESENTATION:
Clarithromycin Tablets USP 250mg:
Packs of 500 &1000 tablets Bulk.
10X10 Blisters
Each Yellow, circular double convex tablet of 11.0mm diameter with "SPC", "SPMC" or "DHS" letters on one side and score mark on the reverse. Each film-coated tablet contains 250 mg of clarithromycin.
Packs of 500 tablets
Each Light orange circular double convex tablets of 12.5mm with "SPC", "SPMC" or "DHS" letters on one side and score mark on the reverse. Each film-coated tablet contains 500 mg of clarithromycin.

INDICATIONS AND DOSE:
Respiratory-tract infections | Mild to moderate skin and soft-tissue infections | Otitis media
Child 1 month–11 years (body-weight up to 8 kg): 7.5 mg/kg twice daily Child 1 month–11 years (body-weight 8–11 kg): 62.5 mg twice daily
Child 1 month–11 years (body-weight 12–19 kg): 125 mg twice daily Child 1 month–11 years (body-weight 20–29 kg): 187.5 mg twice daily
Child 1 month–11 years (body-weight 30–40 kg): 250 mg twice daily Child 12–17 years: 250 mg twice daily usually for 7–14 days, increased to 500 mg twice daily, if required in severe infections (e.g. pneumonia)
Adult: 250 mg twice daily usually for 7–14 days,
Increased to 500 mg twice daily, if required in severe infections (e.g. pneumonia)
Lyme disease
Child *12–17 years*: 500 mg twice daily for 14–21 days
Adult: 500 mg twice daily for 14–21 days
Prevention of pertussis
Child 1 month–11 years (body-weight up to 8 kg): 7.5 mg/kg twice daily for 7 days Child 1 month–11 years (body-weight 8–11 kg): 62.5 mg twice daily for 7 days Child 1 month–11 years (body-weight 12–19 kg): 125 mg twice daily for 7 days Child 1 month–11 years (body-weight 20–29 kg): 187.5 mg twice daily for 7 days Child 1 month–11 years (body-weight 30–40 kg): 250 mg twice daily for 7 days Child 12–17 years: 500 mg twice daily for 7 days
Adult: 500 mg twice daily for 7 days
Helicobacter pylori eradication in combination with a Proton pump inhibitor and amoxicillin
Adult: 500 mg twice daily
Helicobacter pylori eradication in combination with a Proton pump inhibitor and metronidazole
Adult: 250 mg twice daily
Acute sinusitis
Adult: 500 mg twice daily for 5 days

CONTRA INDICATIONS:
Patient with known hypersensitivity to clarithromycin or any other macrolide antibiotic, history of QT prolongation or ventricular cardiac arrhythmia, including torsades de pointes, hypokalaemia, history of cholestatic jaundice or hepatic dysfunction associated with prior use of clarithromycin. Patient receiving terfenadine, astemizole, pimozide, cisapride, ergotamine or dihydroergotamine, and colchicine.

SIDE EFFECTS:
GENERAL SIDE-EFFECTS
Uncommon Burping. dry mouth. muscle complaints. Oral disorders. thrombocytosis. Tremor.
Frequency not known Abnormal dreams. agranulocytosis. depersonalisation . depression. mania. myopathy. psychotic disorder. renal failure. tooth discolouration . urine discolouration

SPECIFIC SIDE-EFFECTS
Uncommon
With oral use Epistaxis
With parenteral use Cardiac arrest. dyskinesia. Haemorrhage. loss of consciousness. pulmonary embolism

USE IN PREGNANCY:
Advice avoid, particularly in the first trimester, unless potential benefit outweighs risk.

BREAST FEEDING:
Advice avoid unless Potential benefit outweighs risk - present in milk.

HEPATIC IMPAIRMENT:
Advises caution in mild-to-moderate impairment; avoid in severe failure if renal impairment also present.

RENAL IMPAIRMENT:
Avoid if severe hepatic impairment also, present. With oral use in adults Avoid clarithromycin m/r preparations if eGFR less than 30 mL/minute/1.73m2. With oral use in children Avoid clarithromycin m/r preparations if estimated glomerular filtration rate less than 30 mL/minute/1.73m2. Dose adjustments. In adults Use half normal dose if eGFR less than 30 mL/minute/1.73m2, max. duration 14 days. In children Use half normal dose if estimated glomerular filtration rate less than 30 mL/minute/1.73m2, max. duration 14 days.

CrCl	Dosage
<30	Half the dose or double the dosing interval.

INTERACTION:
Reduced efficacy with CYP3A inducers (e.g. phenytoin, carbamazepine). Strong inducers of CYP450 system (e.g. efavirenz, rifampicin) may accelerate metabolism, thus lower plasma levels of clarithromycin. Inhibition of metabolism with ritonavir. Torsades de pointes may result from concomitant quinidine or disopyramide. Increased phosphodiesterase inhibitor exposure w/ sildenafil, tadalafil or vardenafil. Increased risk of digoxin toxicity. Decreased concentration of zidovudine. Concomitant use w/ atazanavir, itraconazole or saquinavir may result to bi-directional drug interactions. Hypotension, bradyarrhythmias, and lactic acidosis may result when taken w/ verapamil. Increased risk of myopathy, including rhabdomyolysis with HMG-CoA reductase inhibitors. Increased risk of hypoglycaemia w/ oral hypoglycaemic drugs (e.g. pioglitazone) and insulin. Risk of serious haemorrhage and elevation of INR and prothrombin time w/ oral anticoagulants. Increased ototoxicity with aminoglycosides. Increased and prolonged sedation with triabenzodiazepines (e.g. midazolam). **Potentially Fatal:** Concurrent use with ergot alkaloids (e.g. ergotamine or dihydroergotamine) is associated w/ acute ergot toxicity characterised by vasospasm and ischaemia of the extremities. Concomitant use with astemizole, cisapride, pimozide and terfenadine may result in QT prolongation or ventricular cardiac arrhythmia. Increases serum levels and toxicity of colchicine.

SPECIAL PRECAUTION:
Patient with coronary artery disease, severe cardiac insufficiency, hypomagnesaemia, bradycardia (<50 bpm). May exacerbate symptoms of myasthenia gravis. Renal and hepatic impairment. Pregnancy and lactation.

OVERDASAGE:
Symptoms: Abdominal pain, vomiting, nausea, and diarrhoea.
Management: Prompt elimination of unabsorbed drug and supportive measures.

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

Manufactured by:
State Pharmaceuticals Manufacturing Corporation
No. 11, Sir John Kotalawala Mawatha,
Kandawala Estate,
Ratmalana, Sri Lanka.