150mm

420mm

Spectromax

Film coated tablets

DESCRIPTION
SPECTROMAX is the trade name of Clarithromycin, a systemic macrolide antibiotic.
Each Film- Coated SPECTROMAX 250 and 500 tablet contains 250mg & 500mg Clarithromycin respectively

COMPOSITION
Clarithromycin is : 6-o-methylerythromycin.

EXCIPIENTS : Sodium Starch Glycollate Type A, Anhydrous Calcium Hydrogen Phosphate, Maize Starch, Hydroxypropyl Cellulose, Colloidal Anhydrous Silica, Magnesium Stearate, Purified Talc, HPMC, Titanium dioxide, PEG 400, Quinoline lake yellow, White bees wax.

CLINICAL PHARMACOLOGY
Clarithromycin has in vitro activity against many gram-positive and gram- negative aerobic and anaerobic organisms including methicillin - sensitive Staphylococcus aureus and most Streptococcus species. Clarithromycin is bactericidal against Streptococcus pyogenes and S. Pneumonia, and is active against Haemophilus influenzae. Clarithromycin is active in vivo and in vitro against Mycobacterium leprae and displayed good clinical response with M. chelonae, but is inactive in vitro against M. Tuberculosis Clariythromycin has greater in vitro activiy than erythromycin against Mycobacterium avium complex, Legionella pneumophila, Moraxella (Branhamella) catarrhails, Chlamydia trachomatis, and Ureaplasma urealyticum. It is also active against Neisseria gonorrhoeae, anaerobic gram - positive cocci, Bacteriodes species and Helicobacter pylori.
Clariyhromycin inhibits protein synthesis in susceptible organisms by penetrating cell wall and binding to 50S ribosomal subunits, thereby inhibiting translocation of aminoacyl transfer - RNA and inhibiting polypeptide synthesis.
Clarithromycin is rapidly absorbed from the gastro-intestinal tract, Its gastrointestinal absorption exceeds that of erythromycin.The bioavailability is approximately 55% due to first-pass metabolism, which converts Clarithromycin to its active metabolite, 14- hydroxy-clarithromycin is widely distributed into tissues and fluids and readily enters leukocytes and macrophages. It is primarily excreted by kidneys (20-30%) as parent drug and 10-15% as active metabolite).

INDICATIONS
SPECTROMAX is indicated for the treatment of bacterial exacerbations of bronchitis, acute otitis media streptococcal pharyngitis, mycoplasrna pneumonia, streptococcal pneumonia,acute maxillary sinusitis, and skin and soft tissue infections (e.g., impetigo, cellulitis), when such disease states are caused by susceptible organisms (see Clinical Pharmacology).
SPECTROMAX is indicated for use in combination with proton pump inhibitors for the treatment of Helicobacter pylori infection in patients with an active duodenal ulcer.
SPECTROMAX also has been used orally in other multiple- drug regimens for the treatment of H. plori infection associated with peptic ulcer disease.
SPECTROMAX is indicated in the treatment of disseminated Mycobacterium avium complex, in combination with antimycobacterials to prevent the development of resistance.
SPECTROMAX is also used in the treatment of Legionnaires' disease caused by Legionella pneumophila.

DOSAGE
Usual adult dose
Bacterial exacerbations of bronchitis due to H. influenzae: 500mg every twelve hours for 7 - 14 days.
Bacterial exacerbations of bronchitis due to other organisns: 250mg every twelve hours for 7 -14 days.
Helicobacter pylori infection in patients with an active duodenal ulcer: 500mg three times daily for 14 days.
Disseminated Mycobacterium avium complex ; 500mg every twelve hours.
Streptococcal pharyngitis : 250mg every 12 hours for 10 days.
Pneumonia due to S. Pneumoniae or M. Pneumoniae 250mg every 12 hours for 7 - 14 days.
Acute maxillary sinusitis: 500mg every 12 hours for 14 days.
Skin and soft tissue infections:250mg every 12 hours for 7 - 14 days.
In case of severe renal function impairment, with creatinine clearance below 30ml/minute, doasge is adjusted as follows:
- In conditions requiring 500mg twice daily, the adjusted dose in severe renal impairment is 500mg as a loading dose, then 250mg twice daily.
- In conditions requiring 250mg twice daily, the adjusted dosage is 250mg once daily.

ADVERSE EFFECTS
Clarithromycin is well tolerated. No adverse effect has been reported to occur in more than 3% of patients treated with the drug.
Less frequent effects:Abnormal taste, headache, and gastrointestinal disturbances (abdominal discomfort, pain, diarrhea, nausea and vomiting).
Post-Marketing experience: Showed that as with other macrolides, Clarithromycin has been associated with QT prolongation and ventricular arrhythmias, including ventricular tachycardia and torsades de pointes.
Hepatic dysfunction, including increased liver enzymes, and hepatocellular and/or cholestatic hepatitis with or without jaundice, has been infrequently reported with Clarithromycin. This hepatic dysfunction may be severe and is usually reversible. In very rare instances, hepatic failure with fatal outcome has been reported and generally has been associated with serious underlying diseases and or concomitant medication.

USE IN PREGNANCY
There are no adequate and controlled studies to date in humans. In animals, Clarithromycin has been associated with adverse effects on pregnancy outcome and/or embryo fetal development at dosages thet produced plasma drug concentrations 2-17 times those achieved with the maximum recommended human dosage. Even though the potential risk to fetus has not been clearly elucidated to data, Clarithromycin should be used during pregnancy only in infections for which safer drugs cannot be used or are ineffective. FDA Pregnancy Category C.

USE IN LACTATION
Clarithromycin and its active metabolite are distributed into human breast milk. Caution should be exercised when Clarithromycin is administered to nursing women.

INTERFERENCE WITH CLINICAL AND LABORTORY TESTS
The values of alanine and aspartate aminotransferases and blood urea nitrogen may rarely be elevated with Clarithromycin.

DRUG INTERACTIONS
Clarithromycin may increase plasma concentrations of carbamazepine or digoxin. It is recommended that carbamazepine/digoxin serum levels be monitored upon concurrent use with Clarithromycin.
Rifabutin and rifampicin may decrease Clarithromycin serum concentration by more than 50%.
Clarithromycin increases the area under the plasma concentration time curve (AUC) of theophilline by 17%. Theophylline serum levels monitoring is recommended in patients receiving high doses,or patients with theophylline serum levels in the upper therapeutic range.
Clarithromycin potentiates the effects of warfarin. Prothrombin time should be closely monitored in patients receiving warfarin and Clarithromycin concurrently.
Clarithromycin may zidovudine doses should be taken at least 4 hours apart because Clarithromycin may result in lower peak serum concentration, lower AUC, and delayed time to peak concentration of zidovudine in HIV- infected patients.
Clarithromycin and/or erythromycin inhibits hepatic metabolism of terfenadine, cisapride and pimozide resulting in cardiac arrhythmias (QT prolongation, ventricular tachycardia, ventricular fibrillation and torsades de pointes). Fatalities have been reported.

CONTRAINDICATIONS
Clarithromycin is containdicated in patients with known hypersensitivity to Clarithromycin, erythromycin, or to any other macrolide, due to cross-sensitivity.
Concomitant administration of clariyhromycin with cisapride,pimozide,or terfenadine is contraindicated, and is not recommended in patients receiving astemizole (see Drug Interactions).

WARNINGS
Risk-benefit should be considered in case of severe renal function impairment; because the elimination of Clarithromycin is reduced, especially in patients with a creatinine clearance below 30ml/min. Dose adjustment may be necessary (see Dosage).

OVERDOSE
Following large doses of Clarithromycin, gastro-intestinsal disturbances may occur, and may be accompanied by systemic manifestations.Treatment of overdose includes stomach evacuation by gastric lavage and rapid elimination of unabsorbed drug, followed by supportive and symptomatic measures.

PRECAUTIONS
Antibiotic-associated Clostridium difficile colitis has been rarely reported with the use of many anti-infective agents, including macrolides, and should be considered in patients developing severe or watery diarrhea during or after Clarithromycin therapy.

STORAGE
Store below 30° C. Protect from light and moisture.

PRESENTATION
SPECTROMAX 250 Box containing 14 blistered tablets of Clarithromycin 250mg.
SPECTROMAX 500 Box containing 14 blistered tablets of Clarithromycin 500mg.

THIS IS A MEDICAMENT
. Medicament is product, which affects your health and its consumption contrary to instruction is dangerous for you.
. Follow strictly the doctor's prescription, the method of use and the instruction of the pharmacist who sold the medicament.
. The doctor and the pharamcist are experts in medicine, its benefits and risks.
. Do not by yourself interrupt the period of treatment prescribed for you.
. Do not repeat the same prescription without consulting your doctor.
Keep medicament out of the reach of children.
Council of Arab Health Ministries Union of Arab Pharmacists

Manufactured by :
National Pharmaceutical Industries Co. (SAOG)
Street No 15,Rusayl Industrial Area,
Muscat, Sultanate of Oman.

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