Claricos®

23100

Ref. No: B2123100/22.02

Clarithromycin

Antibacterial

CLARICOS® 250 TABLETS (FILM COATED)
CLARICOS® 500 TABLETS (FILM COATED)
CLARICOS® DRY POWDER FOR SUSPENSION 125MG/5ML

PRESENTATION:
Claricos® 250 Tablets: Yellow, capsule shaped, biconvex film coated tablet embossed '250' on one side and plain on the other side. Each film coated tablet contains: Clarithromycin 250mg, Lactose and other excipients.
Claricos® 500 Tablets: Yellow, capsule shaped, biconvex film coated tablet embossed '500' on one side and plain on the other side. Each film coated tablet contains: Clarithromycin 500mg, Lactose and other excipients.
Claricos® Dry Powder for Suspension 125mg/5ml: White to off white granules which when reconstituted forms a white to off white suspension containing white suspended particles with a fruity flavour. Each 5ml spoonful of the resultant suspension contains: Clarithromycin 125mg.

CLINICAL PHARMACOLOGY:
Clarithromycin is a macrolide antibacterial with a broad and essentially bacteriostatic action against many Gram-positive to a lesser extent some Gram-negative bacteria, as well as other organisms including some *Mycoplasma spp., Chlamydiaceae, Rickettsia spp.*, and *spirochaetes*. Clarithromycin and other macrolides bind reversibly to the 50S subunit of the ribosome, resulting in blockage of the transpeptidation or translocation reactions, inhibition of protein synthesis, and hence inhibition of cell growth. Because macrolides penetrate readily into white blood cells and macrophages there has been some interest in their potential synergy with host defence mechanism in vivo.

Pharmacokinetics:
Clarithromycin is rapidly absorbed from the gastro-intestinal tract following oral administration, and undergoes first-pass metabolism; the bioavailability of the parent drug is about 55%. The extent of absorption is relatively unaffected by the presence of food. Peak concentrations of Clarithromycin and its principal active metabolite 14-hydroxyclarithromycin are reported to be about 1 and 0.6 micrograms/mL respectively following a single 250mg dose by mouth; at steady state the same dose given every 12 hours as tablets produces peak concentrations of Clarithromycin of about 1 microgram/ml. The drug and its principal metabolite are widely distributed, and tissue concentrations exceed those in the serum, in part because of intracellular uptake. Clarithromycin has been detected in breast milk. It is extensively metabolised in the liver, and excreted in the faeces via the bile. The terminal half-life of Clarithromycin is reportedly about 3 to 4 hours in patients receiving 250mg doses twice daily, and about 5 to 7 hours in those receiving 500mg twice daily. The half-life is prolonged in renal impairment.

USES:
Claricos® is given in the treatment of respiratory-tract infections (including otitis media) and in skin and soft tissue infections.
Clarithromycin is also used for the prophylaxis and treatment of opportunistic mycobacterial infections and has been used in the treatment of leprosy. Clarithromycin may be given to eradicate Helicobacter pylori in treatment regimens for peptic ulcer disease. It has been tried with pyrimethamine in protozoal infections, including toxoplasmosis.

DOSAGE AND ADMINISTRATION:
Adults: 250mg twice daily by mouth, increased to 500mg twice daily if necessary in severe infection.
Children: 7.5mg per kg body-weight twice daily.

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For disseminated infection due to Mycobacterium avium complex, 500mg twice daily by mouth, in conjunction with other antimycobacterials.
Leprosy: 500mg daily by mouth has been given as part of an alternative multidrug therapy regimen.
H.Pylori associated with Peptic Ulcer disease: Clarithromycin, usually in an oral dose of 500mg twice daily, is given with another antibacterial and either a proton pump inhibitor or a histamine H_2 - receptor antagonist for 7-14 days.

For reconstitution instructions, refer to label/carton.

CONTRA-INDICATIONS AND WARNINGS:
Clarithromycin should be avoided in those known to be hypersensitive to it, or in those who have previously developed liver disorders while receiving it. It should be used with care in patients with existing liver disease or hepatic impairment.

Adverse Effects:
Gastro-intestinal disturbances are the most frequent adverse effects but are usually mild and less frequent. Taste disturbances, stomatitis, glossitis, tooth discolouration and headache have occurred. There have also been reports of transient CNS effects such as anxiety, dizziness, hallucinations and confusion. Other adverse effects include hypoglycaemia, leucopoenia, and thrombocytopenia.

Interactions:
Increased rifabutin toxicity has been reported in patients receiving Clarithromycin and rifabutin and there has been a report of delirium following concurrent use with fluoxetine.

Pregnancy and Lactation:
Pregnancy: The safety of clarithromycin for use during pregnancy has not been established. Based on variable results obtained from animal studies and experience in humans, the possibility of adverse effects on embryofoetal development cannot be excluded. Therefore, use during pregnancy is not advised without carefully weighing the benefits against risks.
Lactation: The safety of clarithromycin for use during breast feeding of infants has not been established. Clarithromycin is excreted into human breast milk in small amounts.

PHARMACEUTICAL PRECAUTIONS:
Store in a dry place below 25^{0}C. Protect from light. Keep all medicines out of the reach of children.

LEGAL CATEGORY:
Prescription Only Medicine (POM)

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COSMOS
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