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Curazith™

Azithromycin Dihydrate USP

50141

Presentation
Curazith tablet 250mg:
Each coated tablet contains Azithromycin Dihydrate USP equivalent to Azithromycin 250mg.

Curazith tablet 500mg:
Each coated tablet contains Azithromycin Dihydrate USP equivalent to Azithromycin 500mg.

Curazith powder for Bottle of 30ml suspension (200mg/5ml):
After reconstitution each 5ml contains Azithromycin Dihydrate USP equivalent to Azithromycin 200mg.

Clinical Pharmacology:
Azithromycin is acid-stable and can therefore be taken orally with no need of protection from gastric acids. It is readily absorbed; its absorption is greater on an empty stomach. Time to peak concentration in adults is 2.1 to 3.2 hours for oral dosage forms. Due to the high concentration in phagocytes, Azithromycin is actively transported to the site of infection. During active phagocytosis, large concentrations of Azithromycin are released. The concentration of azithromycin in the tissues can be over 50 times higher than in plasma. This is due to ion trapping and the high lipid solubility.
Azithromycin's half-life allows a large single dose to be administered and yet maintain bacteriostatic levels in the infected tissue for several days.
Following a single 500 mg dose, plasma concentrations of Azithromycin declined in a polyphasic pattern with a mean apparent plasma clearance of 630 mL/min and a terminal elimination half-life of 68 hours. The prolonged terminal half-life is thought to be due to extensive uptake and subsequent release of drug from tissues.
Biliary excretion of Azithromycin, predominantly unchanged, is a major route of elimination. Over the course of a week, approximately 6% of the administered dose appears as unchanged drug in urine.
Microbiology:
Azithromycin acts by binding to the 50S ribosomal subunit of susceptible microorganisms and, thus, interfering with microbial protein synthesis. Nucleic acid synthesis is not affected.
Azithromycin has been shown to be active against most isolates of the following microorganisms, both in vitro and in clinical infections:
Aerobic and facultative gram-positive microorganisms:
Staphylococcus aureus, Streptococcus agalactiae, Streptococcus pneumoniae, Streptococcus pyogenes
Aerobic and facultative gram-negative microorganisms:
Haemophilus ducreyi , Haemophilus influenzae , Moraxella catarrhalis , Neisseria gonorrhoeae
"Other" microorganisms:
Chlamydia pneumoniae, Chlamydia trachomatis , Mycoplasma pneumoniae , Beta-lactamase production should have no effect on Azithromycin activity.
Aerobic and facultative gram-positive microorganisms:
Streptococci (Groups C, F, G) , Viridans group streptococci
Aerobic and facultative gram-negative microorganisms:
Bordetella pertussis , Legionella pneumophila
Anaerobic microorganisms:
Peptostreptococcus species , Prevotella bivia

Indications:
Azithromycin is indicated for the treatment of patients with mild to moderate infections caused by susceptible strains of the designated microorganisms in the specific conditions listed below:
Adult:
Acute bacterial exacerbations of chronic obstructive pulmonary disease: due to Haemophilus influenzae, Moraxella catarrhalis or Streptococcus pneumoniae.

Acute bacterial sinusitis: due to Haemophilus influenzae, Moraxella catarrhalis or Streptococcus pneumoniae. Community-acquired pneumonia due to Chlamydia pneumoniae, Haemophilus influenzae, Mycoplasma pneumoniae or Streptococcus pneumoniae in patients appropriate for oral therapy.

Pharyngitis/tonsillitis: caused by Streptococcus pyogenes as an alternative to first-line therapy in individuals who cannot use first-line therapy.

Uncomplicated skin and skin structure infections: due to Staphylococcus aureus, Streptococcus pyogenes, or Streptococcus agalactiae. **Abscesses** usually require surgical drainage.

Urethritis and cervicitis: due to Chlamydia trachomatis or Neisseria gonorrhoeae. ***Genital ulcer*** disease in men due to Haemophilus ducreyi (chancroid).

Pediatric Patients: Acute otitis media caused by Haemophilus influenzae, Moraxella catarrhalis or Streptococcus pneumoniae. Community-acquired pneumonia due to Chlamydia pneumoniae, Haemophilus influenzae, Mycoplasma pneumoniae or Streptococcus pneumoniae in patients appropriate for oral therapy.

Contra-indications:
Azithromycin is contraindicated in patients with known hypersensitivity to Azithromycin, erythromycin, any macrolide or ketolide antibiotic.

Side-Effects:
Most common side effects are gastrointestinal; diarrhea (5%), nausea (3%), abdominal pain (3%) and vomiting. Less than 1% of patients stop taking the drug due to side effects. Serious allergic reactions, nervousness, dermatologic reactions, and fatalities have been reported but are extremely rare. As with all antimicrobial agents, pseudomembranous colitis can occur during and up to several weeks after Azithromycin therapy. This drug may interfere with the effectiveness of birth control pills; other forms of contraception may be required during the treatment period:

Precautions:
General:
Because azithromycin is principally eliminated via the liver, caution should be exercised when Azithromycin is administered to patients with impaired hepatic function.

Pregnancy:
There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, Azithromycin should be used during pregnancy only if clearly needed.

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Lactation:
It is not known whether Azithromycin is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Azithromycin is administered to a nursing woman.

Pediatric Use:
Safety and effectiveness in pediatric patients less than 6 months of age have not been established.

Dose and Administration:
Adults:

Infection*	Recommended Dose/Duration of Therapy
Community-aquired pneumonia (mild severity) Pharyngitis/tonsillitis, Skin/skin structure (uncomplicated)	500 mg as a single dose on Day 1, followed by 250mg once daily on Days 2 through 5.
Acute bacterial exacerbations of chronic obstructive pulmonary disease (mild to moderate)	500 mg QD x 3 days or 500 mg as a single dose on Day 1, followed by 250 mg once daily on Days 2 through 5.
Acute bacterial sinusitis	500 mg QD x 3 days
Genital ulcer disease (chancroid)	One single 1 gram dose
Non-gonoccocal urethritis and cervicitis	One single 1 gram dose
Gonococcal urethritis and cervicitis	One single 2 gram dose
*DUE TO THE INDICATED ORGANISMS (See INDICATIONS.)	

Tablets can be taken with or without food.

Renal Insufficiency:
No dosage adjustment is recommended for subjects with renal impairment (GFR80 mL/min). Caution should be exercised when Azithromycin is administered to subjects with severe renal impairment
Hepatic Insufficiency:
No dose adjustment recommendations can be made in patients with impaired hepatic function.
Pediatric Patients:
Azithromycin for oral suspension can be taken with or without food.
Acute Otitis Media: 30 mg/kg given as a single dose or 10 mg/kg once daily for 3 days or 10 mg/kg as a single dose on the first day followed by 5 mg/kg/day on days 2 through 5.
Acute Bacterial Sinusitis: 10 mg/kg once daily for 3 days.
Community-Acquired Pneumonia:10 mg/kg as a single dose on the first day followed by 5 mg/kg on Days 2 through 5.

Pharyngitis/Tonsillitis: 12 mg/kg once daily for 5 days.

Drug Interactions:
Concomitant administration of Azithromycin may potentiate the effects of oral anticoagulants. Prothrombin times should be carefully monitored while patients are receiving Azithromycin and oral anticoagulants concomitantly.
Drug interaction studies were performed with Azithromycin and other drugs likely to be co-administered When used in therapeutic doses, azithromycin had a modest effect on the pharmacokinetics of atorvastatin, carbamazepine, cetirizine, didanosine, efavirenz, fluconazole, indinavir, midazolam, rifabutin, sildenafil, theophylline (intravenous and oral), triazolam, trimethoprim/sulfamethoxazole or zidovudine. Co-administration with efavirenz, or fluconazole had a modest effect on the pharmacokinetics of Azithromycin No dosage adjustment of either drug is recommended when Azithromycin is coadministered with any of the above agents.
Interactions with the drugs listed below have not been reported in clinical trials with Azithromycin; however, until further data are developed regarding drug interactions when azithromycin and these drugs are used concomitantly, careful monitoring of patients is advised:
Digoxin–elevated digoxin concentrations.
Ergotamine or dihydroergotamine–acute ergot toxicity characterized by severe peripheral vasospasm and dysesthesia.
Terfenadine, cyclosporine, hexobarbital and phenytoin concentrations.

Laboratory Test Interactions:
There are no reported laboratory test interactions.

Warnings:
Serious allergic reactions, including angioedema, anaphylaxis, and dermatologic reactions including Stevens Johnson Syndrome and toxic epidermal necrolysis have been reported rarely in patients on Azithromycin therapy. Although rare, fatalities have been reported. Despite initially successful symptomatic treatment of the allergic symptoms, when symptomatic therapy was discontinued, the allergic symptoms recurred soon thereafter in some patients without further azithromycin exposure. These patients required prolonged periods of observation and symptomatic treatment. The relationship of these episodes to the long tissue half-life of Azithromycin and subsequent prolonged exposure to antigen is unknown at present.
If an allergic reaction occurs, the drug should be discontinued and appropriate therapy should be instituted. Physicians should be aware that reappearance of the allergic symptoms may occur when symptomatic therapy is discontinued.

Storage Condition:
Store below 30°C in dry place.
Do not use later than date of expiry.
Keep all medicine out of the reach of children.
To be dispensed only on the prescription of a registered physician.

Commercial Pack:
Curazith tablet 250mg: 1 x 6's tablet in alu-alu blister pack.
Curazith tablet 500mg: 2 x 6's tablet in alu-alu blister pack.

Manufactured by:
synovia
Synovia Pharma PLC., Station Road, Tongi, Gazipur.
A Subsidiary of **BEXIMCO PHARMA.**

Curazith powder for Bottle of 30ml suspension (200mg/5ml): Box containing sealed cap amber glass bottle containing dry powder for reconstituting 30ml suspension with a 10ml measuring cup and a 1.25ml dropper.

Manufactured for:
synovia
Synovia Pharma PLC., Station Road, Tongi, Gazipur.
A Subsidiary of **BEXIMCO PHARMA.**
by BEXIMCO PHARMA, Tongi, Gazipur. 3021000410

Legend of Packaging Artwork

Name of Printed D/S (Insert)	Curazith 30ml Suspension- D/S (Insert)	
Oracle Code	3021000410	
Synovia Version No	01	
Artwork generation date	03.10.2024	
Dimensions	L-12.8 x W 3.64 inches	
Minimum font size	8 pt	
Color Ref	Pantoen Process Black C ■ Pantone 2347 C ■	
Artwork Prepared By	In House (Anowar Hossain)	
Change Control Ref No		
Artwork Checked By	Quality Control	
	Change Control Coordinator	
	Market Regulatory	
	Marketing	