ZOCIN®

Azithromycin

Composition: Zocin 250mg capsule: Each capsule contains 250mg Azithromycin as Azithromycin dihydrate.
Zocin 200mg suspension: Each 5ml contains 200mg Azithromycin as Azithromycin dihydrate.
Zocin 300mg suspension:Each 7.5ml contains 300mg Azithromycin as Azithromycin dihydrate.

Properties: Azithromycin is an azalide, a subclass of macrolide antibiotics. The mode of action is by inhibition of protein synthesis in bacteria by binding to the 50s ribosomal subunits and preventing translocation of peptides, without affecting polynucleotide synthesis. Zocin demonstrates in vitro activity against a wide range of bacteria including: Gram-positive aerobic bacteria: Staphylococcus aureus, Streptococcus pneumoniae, Streptococcus pyogenes (group A beta-hemolytic streptococci), Streptococcus agalactiae, alpha-hemolytic streptococci (viridans group) and other streptococci and Corynebacterium diphteriae. Azythromycin demonstrates cross resistance with eryrthromycin-resistant gram-positive strains, including Streptococcus faecalis (enterococcus) and most strains of methicillin-resistant Staphylococci.
Gram-negative aerobic bacteria: Hemophilus influenzae and parainfluenzae, Moraxella catarrhalis, Acinetobacter spp., Yersinia spp., Escherichia coli, Bordetella pertussis and parapertussis, Shigella spp., Pasteurella spp., Vibrio cholera and parahaemolyticus, Pleisiomonas shigelloides. Activity against Escherichia coli, Salmonella enteritidis, Salmonella typhi, Enterobacter spp., Aeromonas hydrophila and Klebsiella spp. is variable and susceptibility tests should be performed. Proteus spp., Serratia spp., Mo[illegible]a spp. and Pseudomonas aeruginosa are usually reristant.
Beta-Lactamase [illegible]tion should have no effect on Zocin activity.
Anaerobic bacteria: Bacteroids fragilis, Bacteroids spp., Clostridium perfringens, Peptococcus spp., Peptostreptococcus spp., Fusobacterium necrophorum and Proprionibacterium acnes.
Organisms of sexually transmitted diseases: Chlamydia trachomatis, Neisseria gonorrhoeae, Treponema pallidum and Haemophilus ducreyi.
Other microorganisms: Borrelia burgdorferi (Lyme disease agent), Chlamydia pneumoniae, Toxoplasma gondii, Mycoplasma pneumonia, Mycoplasma hominis, Ureaplasma urealyticum, Pneumocystis carinii, Mycobacterium avium, Campylobacter spp., and Listeria monocytogenes.

Pharmacokinetic properties: Following oral administration, Azithromycin is rapidly absorbed and widely distributed into tissues causing significantly higher concentration in tissues than in plasma (up to 50 times the maximum observed concentration in plasma). Concentrations in target tissues such as lung, tonsils and prostate exceed the MIC90 for likely encountered pathogens after a single dose of 500mg. A mean terminal serum elimination half-life of 57 hours has been reported for Azithromycin. The time to peak plasma levels is 2-3 hours. Approximately 12% of an intravenously administered dose is excreted in urine over 3 days as the parent drug, the majority in the first 24 hours. Very high concentrations of unchanged drug have been found in human bile, together with 10 inactive metabolites, formed by N- and O-demethylation, by hydroxylation of the desosamine and aglycone rings, and by cleavage of the cladinose conjugate.

Indications: Zocin is indicated for the treatment of a wide range of infections caused by susceptible organisms, specifically: Upper respiratory tract infections including pharyngitis, tonsillitis, sinusitis and otitis media.Lower respiratory tract infections including bronchitis and pneumonia. Odontostomatological infections. Skin and soft tissue infections.Sexually transmitted diseases (non-gonococcal urethritis and cervicitis).

Dosage and administration: Adults: Respiratory tract infections: a single 500 mg once daily for 3 days.
Skin and soft tissue infections: a single 500 mg once daily for 3 days.
Sexually-transmitted diseases: 1gram given as a single dose.
Zocin should be administered as a single daily dose at least one hour before or two hours after meals.

Children: The usual dose for Zocin is 10 mg/kg body weight given as a single dose for 3 days.
For pediatric streptococcal pharyngitis, azithromycin given as a single dose of 10mg/kg or 20mg/kg for 3 days has been shown to be effective; however, do not exceed a daily dose of 500mg. in clinical trials comparing these two dosage regimens, similar clinical efficacy was observed but greater bacteriological eradication was evident at the 20mg/kg/day dose.
Zocin powder for oral suspension may be taken with or without food. The prior ingestion of food may ameliorate any gastrointestinal side effects caused by the administration of azithromycin.
No information is available on children under 6 months of age.

Precautions: The use of broad-spectrum antibiotics may lead to overgrowth of non-susceptible organisms.
Pseudomembranous colitis may occur in patients under treatment with broad-spectrum antibiotics. No dosage adjustment is required in patients with mild renal impairment (creatinine clearance > 40ml/min), but there are no data regarding azithromycin usage in patients with a creatinine clearance < 40ml/min. Thus caution should be exercised in using azithromycin in these patients.
In patients with mild to moderate hepatic impairment, there is no evidence of a marked change in serum pharmacokinetics of azithromycin compared to those with normal hepatic function. No dose adjustment is recommended for patients with mild to moderate hepatic impairment; nonetheless, since liver is the principal route of elimination, the use of Zocin should be undertaken with caution in patients with liver disease or with severe hepatic impairment. Rare serious allergic reactions including angioedema and anaphylaxis have been reported in patients on macrolide therapy. There are no adequate and well-controlled studies in pregnant women, however, studies on animals provide no evidence of harm to the fetus (pregnancy category B). No data on secretion of Azithromycin in breast milk is available, Therefore, caution should be exercised when azithromycin is given to nursing mothers.

Contraindications: Zocin is contraindicated in patients with a known hypersensitivity to Azithromycin or any of the macrolide antibiotics.Severe hepatic insufficiency.Azithromycin is generally contraindicated during pregnancy and lactation, and in the very early infancy.

Warnings: Because of the theoretical possibility of ergotism. Azithromycin and ergot derivatives should not be co-administered.

Side effects: Azithromycin is well tolerated with a low incidence of side effects. The majority of side effects were gastrointestinal in origin such as nausea, abdominal discomfort, vomiting, flatulence and diarrhea. As with other macrolides, allergic reactions and reversible elevations in liver transaminases were reported.

Adverse events reported with azithromycin during the post-marketing period in adult and/or pediatric patients for which a causal relationship may not be established include:

Gastrointestinal: Anorexia, constipation, dyspepsia, flatulence, vomiting/diarrhea rarely resulting in dehydration.

Special Senses: Hearing impairment has been reported with macrolide antibiotics. There have been reports of reversible hearing impairment including hearing loss, deafness, and/or tinnitus in some patients with prolonged use of high doses of azithromycin. There have been rare reports of taste disturbances.*Genitourinary:* Interstitial nephritis and acute renal failure.*Hematopoietic:* thrombocytopenia. Transient episodes of mild neutropenia have occasionally been observed, although a causal relationship to azithromycin has not been established.Liver/Biliary: Abnormal liver function including hepatitis and cholestatic jaundice have been reported, as well as rare cases of hepatic necrosis and hepatic failure, which have rarely resulted in death. However, a causal relationship to azithromycin has not been established.

Musculoskeletal: arthralgia.*Psychiatric:* aggressive reaction, nervousness, agitation, and anxiety.

Reproductive: vaginitis.*Nervous System:* dizziness, vertigo, convulsions, headache, somnolence, paresthesia and hyperactivity.*Skin/Appendages:* allergic reactions including pruritis, rash, photosensitivity, edema, urticaria and angioedema. Rarely, serious skin reactions including erythema multiforme, Stevens Johnson Syndrome, and toxic epidermal necrolysis have occurred.*Cardiovascular:* palpitations and arrhythmias including ventricular tachycardia (as seen with other macrolides) have been reported although a causal relationship to azithromycin has not been established.*General:* Asthenia has been reported although a causal relationship to azithromycin has not been established, moniliasis and anaphylaxis have occurred.

Drug interactions: In patients receiving azithromycin and antacids, the two drugs should not be taken at the same time. Administration of cimetidine two hours prior to azithromycin had no effect on azithromycin absorption. The effect of azithromycin on cyclosporine is unknown, and caution should be exercised before coadministration. No clinically significant interactions have been observed between azithromycin and theophylline, digoxin, methylprednisolone or carbamazepin; however, with other macrolides the following interactions were observed: theophylline: increase in the plasma concentrations of theophylline; digoxin: elevated digoxin levels; triazolam: decrease in the clearance of triazolam with a possible increase in the pharmacologic effect of triazolam; drugs metabolized by the cytochrome p-450 system: elevations in serum carbamazepine, cyclosporine, and phenytoine levels.

Azithromycin did not affect the prothrombin time response to a single dose of warfarin. There have been reports received in the post-marketing period of potentiated anticoagulation subsequent to coadministration of azithromycin and coumarin-type oral anticoagulants. Although a causal relationship has not been established, consideration should be given to the frequency of monitoring prothrombin time.

As regards the concomitant use of azithromycin and other anticoagulant drugs, since no specific drug interaction studies have been performed, careful monitoring of patients taking these drugs concomitantly is advised.

Pharmacokinetics studies have reported no evidence of an interaction between azithromycin and terfenadine. There have been rare cases reported where the possibility of such an interaction could not be entirely excluded; however, there was no specific evidence that such an interaction occurred.

Because of the theoretical possibility of ergotism, azithromycin and ergot derivatives should not be coadministered. Coadministration of azithromycin and rifabutin did not affect the serum concentrations of either drug.Neutropenia was observed in subjects receiving concomitant treatment of azithromycin and rifabutin. Although neutropenia has been associated with the use of rifabutin, a causal relationship to combination with azithromycin has not been established.

Single 1000mg doses and multiple 1200 or 600mg doses of azithromycin did not affect the plasma pharmacokinetics or urinary excretion of zidovudine or its glucuronide metabolite. However, administration of azithromycin increased the concentrations of phosphorylated zidovudine, a clinically active metabolite, in peripheral blood mononuclear cells. The clinical significance of this finding is unclear, but it may be beneficial to patients.

Overdosage: Adverse events were experienced in higher than recommended doses were similar to those seen at normal doses. In the event of overdosage, general supportive measures are indicated as required.

Presentations available :

Zocin is available as 250mg capsule in 6 capsules pack.
Zocin is available as 200mg/5ml suspension in 15ml bottle.
Zocin is available as 300mg/7.5ml suspension in 22.5ml bottle.

This is a Medicament :
- Keep all medicaments away from children.
- A medicament is a product that affects your health, and its consumption contrary to instructions is dangerous.
- Strictly follow the doctor's prescription, the method of use and the instructions of the pharmacist who dispensed the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not interrupt the treatment before consulting your doctor.
- Do not repeat the same prescription without consulting your doctor.

Advanced Pharmaceutical Industries Co. Ltd.
P.O.Box 925482, Amman 11110- Jordan

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