MEDLEY PHARMACEUTICALS

Z-Cin Capsules

(AZITHROMYCIN)

Composition:
Each Capsule contains:
Azithromycin (as dihydrate) USP 250mg

Properties:
Azithromycin is an azalide, derived from the macrolide class of antibiotics. Azithromycin demonstrates activity in vitro, against wide range of Gram-positive bacteria including staphylococcus aureus ,Streptococcus pneumoniae, streptococcus pyogenes (Group A) and other streptococcus species; Haemophilus influenzae and Para-influenzae ; Moraxella catarrhalis ;anaerobes including Bacteroids fragilis ;Escherichia coli; Bordetella pertussis ;Bordetella parapertussis, Borrella burgdogferi; Haemophilus ducreyi; Neisseria gonorrhoeae and Chlamydia trachomatis. Azithromycin also Demonstrates in-vitro activity against Legionella Pneumophila , Mycoplasma pneumonia and hominis, Campylobacter sp., Toxoplasma gondii and Treponema pallidum.

Pharmacokinetics:
Following oral administration in humans, Azithromycin is widely distributed throughout the body; bioavailability is approximately 37%. The time taken to reach peak plasma levels is 2-3 hours; plasma terminal elimination half-life closely reflects the tissue depletion half-life of 2 to 4 days. Kinetic studies have shown markedly higher Azithromycin levels in tissues than in plasma (up to 50 time the maximum observed concentration in plasma) indicating that the drug is highly tissue bound. Concentrations in target tissue such as lungs, tonsils and prostate exceed the MIC90 for likely pathogens after a single dose of 500mg.

Indications:
Azithromycin is indicated for infections caused by susceptible organisms; in lower respiratory tract infections including bronchitis and pneumonia, in upper respiratory tract infections including otitis media, pharyngitis /tonsillitis and sinusitis, skin and soft tissue infections and acne, mild to moderate typhoid fever caused by multi-drug resistant strain. In sexually transmitted diseases in men and women, azithromycin is indicated in the treatment of uncomplicated genital infections due to Chlamydia trachomatis.
Azithromycin is indicated as second line therapy for Typhoid fever caused by S. typhi and S.para typhi.

Dosage and Administration:
Azithromycin should be administered as a single dose, and as common with many other antibiotics, should be taken at least 1 hour before or 2 hours after food.

Adults:
For respiratory tract infections and skin and soft tissue infections the total dose is 1.5 gm which should be given as 500mg as a single dose daily for 3 days. Alternatively as initial dose of 500mg in the 1st day may be followed by 250mg daily for further 4 days.

Manufactured by:
ISO 9001-2008 Certified Company
Medley Pharmaceuticals
41-A, P.S.I.E. Jhang Bahtar Road,
Wah Cantt- Rawalpindi

For sexually transmitted diseases caused by Chlamydia trachomatis, the dose is 1g given as a single dose. For typhoid fever, the dose is 500mg to 1000mg once daily for 5-7 days.

Use in children:

There is no information in children less than six months of age. The dose in children is 10mg /kg as a single daily dose for 3 days .For typhoid fever therapy should be given for 7 days.

Contra-indications:

Azithromycin is contra-indicated in patients with a known hypersensitivity to Azithromycin or any macroclide antibiotics.

Precautions and warnings:

As with any antibiotic, observation for signs of super infection with non susceptible organisms including fungi is recommended as with erythromycin and other macrolides serious allergic reactions, including angioheurotic edemas and anaphylaxis have been reported. Some of these reactions with Azithromycin have resulted in recurrent symptoms and required a long period or observation and treatment.

Use in renal impairment:

No dosage adjustment is needed in patients with mild renal impairment (creatinine clearance>40 ml/min.) but there are no data regarding Azithromycin usages in patients with more severe renal impairment. Thus caution should be exercised in using Azithromycin in these patients.

Use in hepatic impairment:

As liver is the principal route of excretion of Azithromycin, it should not be used in patients with hepatic disease

Use during pregnancy and lactation: Use in pregnancy;

Animal reproduction studies have demonstrated that Azithromycin crosses the placenta, but have revealed no evidence of harms to the fetus. There are no adequate and well controlled studies in pregnant women .Since animal reproduction studies are not always predictive of human response, Azithromycin should be used during pregnancy only if adequate alternatives are not available.

Use In lactation;

No data on secretion of Azithromycin in breast milk are available, so Azithromycin should only be used in lactating women where adequate alternatives are not available.

Drug interactions:

Antacids:

In patients receiving Azithromycin and antacids, Azithromycin should be taken at least 1 hour before or 2 hours after the antacids.

Carbamazepine:

In a pharmacokinetics interaction, study in healthy volunteers, no significant effect was observed on the plasma level of Carbamazepine or its active metabolite.

Cyclosporine:

Some of the related macrolide antibiotics interfere with the metabolism of cyclosporine. In the absence of pharmacokinetics studies or clinical data investigating potential interaction between Azithromycin and cyclosporine, caution should be exercised before co- administration of these

two drugs. If co-administration is necessary, cyclosporine levels should be monitored and the dose adjusted accordingly.

Digoxin:

No interaction has been reported in patients who have received concomitant azithromycin and cardiac glycosides. However, some of the macrolide antibiotics have been reported to impair the metabolism of digoxin (in the gut) in some patients. Therefore in patients receiving concomitant azithromycin and digoxin the possibility of raised digoxin levels should be borne in mind.

Ergot derivatives:

Because of the theoretical possibility of egotism, Azithromycin and ergot derivatives should not be co-administered.

Warfarin:

In a pharmacokinetics interaction study, azithromycin did not alter the anticoagulant effect of a single 1.5 mg dose of warfarin administered in healthy volunteers. Azithromycin and warfarin may be co-administered but monitoring of the prothrombin time should be continued as routinely performed.

Side-effects:-

Azithromycin is well tolerated with a low incidence of side effects. Most side-effects observed were mild to moderate in severity. The majority of side-effects were of gastrointestinal origin with nausea, abdominal discomfort (pain/cramps), vomiting, flatulence, diarrhea and loose stools being occasionally observed. Allergic reactions such as rashes have occurred and there have also been rare reports of serious hypersensitivity reactions. Reversible elevations in liver transaminases have been seen with a frequency similar to the comparative macrolide and penicillins, used in clinical trials. Transient mild reductions in neutrophils counts have occasionally been observed in clinical trials, although a casual relationship to azithromycin has not been established.

Over dosage:

There is no data on over dosage with azithromycin .Typical symptoms of over dosage with macrolide antibiotics include hearing loss, severe nausea, vomiting and diarrhea. Gastric level and general supportive measures are indicated.

Storage condition:

Protect from heat, light and moisture.

Warning:

All drugs should be kept out of the reach of children.

Presentation:

Blister of 1x10 capsules

.