WINZITH®

(A z i t h r o m y c i n)

Presentation:
Each Film Coated Tablet contains:

WINZITH® 250mg Tablet.
Azithromycin (as dihydrate) USP 250mg

WINZITH® 500mg Tablet.
Azithromycin (as dihydrate) USP 500mg

Properties:
Azithromycin is an azalide, derived from the macrolide class of antibiotics.
Azithromycin demonstrates activity In-vitro, against a wide range of gram-positive and gram-negative bacteria including staphylococcus aureus, streptococcus pneumoniae streptococcus pyogenes (Group A) and other streptococcal species, Haemophilus influenzae and para-influenzae, moraxella catarrhalis, anaerobes including Bacteroids Fragilis, Escherichia coli, Bordetella pertussis, Bordetella parapertussis, Borrelia burgdorferi, Haemophilus ducreyi, Neisseria gonorrhoeae and Chlamydia trachomatis.

Azithromycin also demonstrates in-vitro activity against Legionella pneumophila, Mycoplasma pnemoniae and hominis, campylobacter sp., Toxoplasma gondii and Treponema pallidum.

Pharmacokinetics:

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

Indications:

Azithromycin is indicated for infection caused by susceptible organisms; in lower respiratory tract infection including bronchitis and pneumonia, skin and soft tissue infections, Otitis media and in upper respiratory tract infections including sinusitis, pharyngitis / tonsillitis and Acne vulgaris.
In sexually transmitted diseases in men and women Azithromycin is indicated in the treatment of uncomplicated genital infections due to Chlamydia trachomatis.

Dosage and administration:

WINZITH® tablet should be administered as single dose and can be taken with or without food.

Adults:
For all indications except sexually transmitted diseases, the total dose is 1.5 g which should be given as 500mg as a single dose daily for 3 days. Alternatively in initial dose of 500mg in the first day followed by 250mg daily for further 4 days.
For sexually transmitted diseases caused by Chlamydia trachomatis the dose is 1g given as a single dose.

Use in children:
There is no information on children under six months of age. The dose in children is 10 mg / kg as a single daily dose for 3 days.

AGE (YRS)	WEIGTH (KG)	DOSAGE (10mg/kg)
0.5 - 2.0	4.5-12.0	1.5-3.0ml (45-120 mg)
2.5-4.0	14.0-16.0	3.5-4.0ml (140-160mg)
4.5-6.0	17.0-20.5	4.5-5.0ml (170-205mg)
6.5-8.0	21.5-25.0	5.0-6.5ml (215-250mg)
8.5-10.0	26.5-31.0	6.5-8.0ml (265-310mg)
10.5-12.0	33.0-40.0	8.5-10.5ml (330-400mg)
12.5-14.0	41.0-50.5	11.0-12.5ml (410-505mg)
14.5-16.0	52.0-62.0	13.5-15.5ml (520-620mg)
16.5-18.0	64.0-69.0	16.0-17.0ml (640-690mg)

Contra-indications:
Azithromycin is contra-indicated in patients with a known hypersentivity to Azithromycin or any macrolide antibiotics.

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

Precautions and warnings:
As with any antibiotics, observation for signs of superinfection with nonsuscepitible organisms, including fungi is recommended. As with erythromycin and other macrolides, serious allergic reactions, including angioneurotic oedema and anaphylaxis, have been reported. Some of these reactions with Azithromycin have resulted in recurrent symptoms and required a long period of 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 usage in patients with more severe renal impairments, thus caution should be exercised in using Azithromycin in these patients.

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

Use in pregnancy:

Animal reproduction studies have demonstrated that Azithromycin crosses the placenta, but have revealed no evidence of harm to the foetus. 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 regarding secretion of Azithromycin in breast milk are available, so Azithromycin should only be used 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 levels of carbamazepine or its actives 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 is necessary, cyclosporin levels should be monitored and the dose adjusted accordingly.

Digoxin:

No interaction have 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 gout) 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 ergotism, 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 15 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 side effects. Most side effects observed were mild to moderate in severity. The majority of side-effects were of gastrointestinal orgin 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 with a frequency similar to the comparative macrolides and penicillins used in clinical trails. Transient mild reductions in neutrophil counts occasionally been oberved in clinical trails, although, a casual relationship to Azithromycin has not been established.

Overdosage:

There are no data of overdosage with Azithromycin. Typical symptoms of overdosage with macrolides antibiotics include hearing loss, severe nausea, vomiting diarrhea. Gastric lavage and general supportive measures are indicated.

Dosage & Instructions:
As advised by the physician. Keep all medicines out of the reach of children.
Protect from light, heat and moisture. To be sold on the prescription of a registered medical Practitioner only. Store between 20 °C to 25 °C.
(Excursion permitted between 15 °C to 30 °C.)

How Supplied:

WINZITH® **250mg Tab.** Pack of 1x6

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