ZITHROX®

Azithromycin dihydrate BP film coated tablet and powder for suspension

DESCRIPTION

ZITHROX® is a preparation of Azithromycin. Azithromycin is an antibiotic of azalide group. It is active against wide range of gram-positive and gram-negative organisms. Azithromycin is widely distributed throughout the body. Peak plasma level is achieved within 2-3 hours. Pharmacokinetic studies show higher Azithromycin concentrations in tissues than in plasma. Concentrations in target tissues such as lung, tonsil, prostate etc. exceed the MIC for susceptible pathogens after a single dose of 500 mg.

INDICATIONS

Azithromycin is indicated for infections caused by susceptible organisms; in lower respiratory tract infections including bronchitis and pneumonia, skin and soft tissue infections, otitis media and in upper respiratory tract infections including sinusitis, pharyngitis, and tonsilitis. In sexually transmitted diseases in men and women, Azithromycin is indicated in the treatment of uncomplicated genital infections due to *Chlamydia trachomatis* (an intracellular bacteria responsible for eye, genital infection).

DOSAGE AND ADMINISTRATION

ZITHROX® should be taken at least 1 hour before or 2 hours after food.

Adults: For most indications, the total dose is 1.5 g which should be given as 500 mg once daily for 3 consecutive days or alternatively, a single dose of 500 mg on day 1 followed by 250 mg once daily on days 2-5.

For sexually transmitted diseases caused by *Chlamydia trachomatis* the dose is 1 g as a single dose.

Elderly: Normal adult dosage is recommended.

Children: The dose in children over 6 months of age is 10 mg/kg/day as a single dose for 3 days. There is no information on children under 6 months of age.

CONTRAINDICATIONS

It is contra-indicated in patients with known hypersensitivity to Azithromycin or any of the macrolide antibiotics. Because of theoretical possibility of ergotism, Azithromycin and ergot derivatives should not be co-administered.

As with erythromycin and other macrolides, rare serious allergic reactions have been reported.

PRECAUTIONS

Because Azithromycin principally eliminated via the liver, caution should be exercised when Azithromycin is administered in patients with impaired hepatic function. No dose adjustment is needed in patients with mild renal impairment (creatinine clearance>40 ml/min), but there is no data regarding Azithromycin usage in patients with more severe renal impairment, thus caution should be exercised in using Azithromycin in these patients. As with any antibiotic, observations for signs of superinfection with non-susceptible organisms, including fungi, is recommended.

Azithromycin should not be concomitantly used with astemizole or terfenadine.

USE IN PREGNANCY AND LACTATION

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. Azithromycin should be used during pregnancy only if adequate alternatives are not available. 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.

SIDE-EFFECTS

Azithromycin is well tolerated with a low incidence of adverse effects. Most adverse effects observed were mild to moderate in severity. The majority of adverse effects were gastrointestinal in origin with nausea, abdominal discomfort, vomiting, flatulence, diarrhoea and loose stools being occasionally observed.

DRUG INTERACTION

In patients receiving Azithromycin and antacid, Azithromycin should be taken at least 1 hour before or 2 hours after antacid. Caution should be exercised before co-administration of Azithromycin and cyclosporin. If co-administration is necessary, cyclosporin levels should be monitored and the dose adjusted accordingly. In patients receiving concomitant Azithromycin and digoxin, the possibility of raised digoxin levels should be borne in mind. Azithromycin and warfarin may be co-administered, but monitoring of the prothrombin time should be routinely performed. No significant drug interaction between Azithromycin and carbamazepine, cimetidine, methylprednisolone or theophylline has been observed.

OVERDOSE

There are no data on overdose with Azithromycin. Typical symptoms of overdose with macrolide antibiotics include hearing loss, severe nausea, vomiting and diarrhoea. Gastric lavage and general supportive measures are indicated.

PHARMACEUTICAL PRECAUTIONS

Store in dry place and away from light. Keep out of reach of children.

PACKAGING

ZITHROX® 250 Tablet : Box containing 2 strips of 6 tablets each. Each film coated tablet contains Azithromycin Dihydrate BP equivalent to Azithromycin 250 mg.

ZITHROX® 500 Tablet : Box containing 2 strips of 6 tablets each. Each film coated tablet contains Azithromycin Dihydrate BP equivalent to Azithromycin 500 mg.

ZITHROX®
Powder for suspension : Bottle containing dry powder for preparation of 20 ml/ 35 ml/ 50 ml suspension. After reconstitution, each 5 ml contains Azithromycin Dihydrate USP equivalent to Azithromycin 200 mg.

SK+F

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