For mild or moderate typhoid caused by multidrugresistant strains, 500 mg once daily may be given for 7 days.
For details of doses in infants and children, see below. Azithromycin dihydrate may also be given initially by intravenous infusion to adults in doses equivalent to 500 mg of azithromycin as a single daily dose in the treatment of community-acquired pneumonia and pelvic inflammatory disease; treatment should be changed to the oral route after at least 2 days in pneumonia and after 1 or 2 days in pelvic inflammatory disease. It may be given either in a solution containing 1 mg/mL over 3 hours or in a solution containing 2 mg/mL over 1 hour.
Intravenous Administration After reconstitution and dilution, the recommended route of administration for intravenous azithromycin is by IV infusion only. Do not administer as an intravenous bolus or an intramuscular injection. The infusate concentration and rate of infusion for azithromycin intravenous (IV) should be either 1 mg/ml over 3 hours or 2 mg/ml over 1 hour. An intravenous dose of 500 mg azithromycin should be infused for a minimum duration of one (1) hour.
Administration in children.
Azithromycin is licensed for use in infants and children and the usual oral dose in those over 6 months of age is 10 mg/kg once daily for 3 days, or an initial dose of 10 mg/kg may be followed by 5 mg/kg daily for a further 4 days; those who weigh over 45 kg may be given the usual adult dose (see above). A single dose of 30 mg/kg may also be given for acute otitis media. For pharyngitis or tonsillitis in children aged over 2 years, 12 mg/kg once daily for 5 days may be given. US official guidelines suggest that for prophylaxis of disseminated *Mycobacterium avium* complex infections, azithromycin 20 mg/kg (to a maximum of 1.2 g) once weekly or 5 mg/kg (to a maximum of 250 mg) once daily may be given. For treatment, 10 to 12 mg/kg (to a maximum of 500 mg) once daily should be given with other antimycobacterials.
In the UK, the *BNFC* suggests that azithromycin may be used in penicillin allergic children for the prevention of secondary cases of group A streptococcal infection; those 6 months and older may be given an oral dose of 12 mg/kg (to a maximum of 500 mg) once daily for 5 days. The *BNFC* also suggests giving azithromycin 10 mg/kg once daily for 7 days in the treatment of mild to moderate typhoid caused by multidrug-resistant strains in those aged 6 months and over.
ADVERSE EFFECTS
Gastrointestinal disturbances are the most frequent adverse effect of azithromycin but are usually mild and less frequent than with erythromycin. Headache, somnolence, and taste disturbances may occur. Severe hypersensitivity reactions occur rarely but may be prolonged. Thrombocytopenia and mild transient neutropenia have been rarely reported in patients receiving azithromycin. Pain and inflammation may occur at the site of intravenous infusions particularly at high concentrations. Licensed product information states that azithromycin should be used with caution in patients with hepatic or renal impairment. It should not be given to those with severe hepatic impairment as safety has not been established. Although plasma concentrations may be increased in renal impairment dosage adjustment is not usually required.
Before taking this medicine
You should not use azithromycin if you are allergic to it, or if:
· you have ever had jaundice or liver problems caused by taking azithromycin; or
· You are allergic to similar drugs such as clarithromycin, erythromycin, or telithromycin.
To make sure azithromycin is safe for you, tell your doctor if you have ever had:
· liver disease;
· kidney disease;
· myasthenia gravis;
· a heart rhythm disorder;
· low levels of potassium in your blood; or
· long QT syndrome (in you or a family member).

This medicine is not expected to harm an unborn baby. Tell your doctor if you are pregnant or plan to become pregnant.

It is not known whether azithromycin passes into breast milk or if it could harm a nursing baby. Tell your doctor if you are breast-feeding a baby.
Interactions
For a discussion of drug interactions of macrolide antibacterials, Giving azithromycin with antacids containing aluminium or magnesium salts can reduce the rate, but not the extent, of its absorption; azithromycin should be given at least 1 hour before or 2 hours after the antacid.
Statement on Usage during Pregnancy and Lactation
Animal reproduction studies have been performed at doses up to moderately maternally toxic dose concentrations. In these studies, no evidence of harm to the fetus due to azithromycin was found. There are, however, 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.
Storage: - Store at 20° C to 25°C (68° to 77°F) see U.S.P. controlled room Temperature Protected from Light and moisture.
Improper Storage may deteriorate the product
Medicine: - Keep out of reach of children.
Presentation: - Each pack contain 500 mg of Azithromycin in a vial. And a Sterile Water for Injection IP

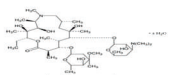
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For the use only of a registered medical practitioner or a hospital or a laboratory

℞ Azithromycin For Injection U.S.P.

AZEECAN 500
Injection

For IV Infusion Use Only
Composition:-
Each Vial Contains:-
Azithromycin Dihydrate (Sterile) (Lyophilized) I.P
eq. to anhydrous Azithromycin 500 mg.
DESCRIPTION
Azithromycin for injection contains the active ingredient azithromycin, a subclass of macrolide antibiotics, for intravenous injection. Azithromycin has the chemical name (2R,3S,4R,5R,8R,10R,11R,12S,13R,14R)-13-[2,6-dideoxy-3-C-methyl-0-methyl-a-L-ribo- hexopyranosyl)oxy]-2-ethyl-3,4,10-trihydroxy-3,5,6,8,10,12,14-heptamethyl-11-[[3,4,6-trideoxy- 3-(dimethylamino)-ll-n-xy/o- hexopyranosyl]oxy]-1-oxa-6-azacyclopentadecan-15-one monohydrate or dihydrate. Azithromycin is derived from erythromycin; however, it differs chemically from erythromycin in that a methyl-substituted nitrogen atom is incorporated into the lactone ring. Its molecular formula is $C_{38}H_{72}N_2O_{12}$, and its molecular weight is 749.00. Azithromycin has the following structural formula:-



Azithromycin

PHARMACOLOGY
PHARMACOKINETICS
Azithromycin given orally is rapidly absorbed and about 40% bioavailable. Absorption from capsules, but not tablets or suspension, is reduced by food. Peak plasma concentrations occur 2 to 3 hours after an oral dose and 1 to 2 hours after intravenous dosage. However, azithromycin is extensively distributed into the tissues, and tissue concentrations subsequently remain much higher than those in the blood; in contrast to most other antibacterials, plasma concentrations are therefore of little value as a guide to efficacy. High concentrations are taken up into white blood cells. There is little diffusion into the CSF when the meninges are not inflamed. Data from *animal* studies indicate that azithromycin crosses the placenta. Small amounts of azithromycin are demethylated in the liver, and it is excreted in bile mainly as unchanged drug and a number of inactive metabolites have also been detected. About 6% of an oral dose (representing about 20% of the amount in the systemic circulation) is excreted in the urine. The terminal elimination half-life is about 68 hours
ANTIMICROBIAL ACTION
Azithromycin is less active than erythromycin against streptococci and staphylococci, but has greater activity than erythromycin *in vitro* against some Gram-negative organisms such as *Haemophilus influenzae* and *Moraxella catarrhalis* (*Branhamella catarrhalis*), as well as having activity against some of the Enterobacteriaceae such as *Escherichia coli* and *Salmonella* and *Shigella* spp. Azithromycin is also more active than erythromycin against *Chlamydia trachomatis* and *Ureaplasma urealyticum*, and some opportunistic mycobacteria, including *Mycobacterium avium* complex. It has activity against the protozoa *Toxoplasma gondii* and *Plasmodium falciparum*.
USES AND ADMINISTRATION
Azithromycin is a nitrogen-containing macrolide with actions and uses similar to those of erythromycin. It is given in the treatment of respiratory- tract infections (including otitis media), in skin and soft-tissue infections, and in uncomplicated genital infections. Azithromycin may also be used for the prophylaxis, and as a component of regimens in the treatment, of *Mycobacterium avium* complex (MAC) infections. It is used in some countries for the prophylaxis of endocarditis in at-risk patients unable to take penicillin. It is also used in the management of trachoma and typhoid.
For details of all these infections and their treatment, see under Choice of Antibacterial. Azithromycin has been tried in protozoal infections such as babesiosis (below), crytosporidiosis , and toxoplasmosis.
Adults For the treatment of adult patients with CAP due to the indicated organisms, the recommended dose of intravenous azithromycin is 500 mg as a single daily dose by the IV route for at least two days. Intravenous therapy should be followed by oral azithromycin as a single daily dose of 500 mg to complete a 7 to 10 day course of therapy. The timing of the conversion to oral therapy should be done at the discretion of the physician and in accordance with clinical response. For the treatment of adult patients with PID due to the indicated organisms, the recommended dose of intravenous azithromycin is 500 mg as a single dose by the IV route for one or two days. Intravenous therapy should be followed by azithromycin by the oral route at a single daily dose of 250 mg to complete a 7-day course of therapy. The timing of the conversion to oral therapy should be done at the discretion of the physician and in accordance with clinical response. If anaerobic microorganisms are suspected of contributing to the infection, an antimicrobial anaerobic agent may be administered in combination with azithromycin
For uncomplicated genital infections caused by *Chlamydia trachomatis* and for chancroid, 1 g of azithromycin is given as a single dose. A single dose of 2 g has been given for uncomplicated gonorrhoea. For the treatment of granuloma inguinale, an initial dose of 1 g followed by 500 mg daily may be given, or 1 g may be given once a week for at least 3 weeks, until all lesions have completely healed.
In the USA, a modified-release preparation given as an oral suspension is available. The product delivers a single dose of 2 g and should also be taken on an empty stomach. It is licensed for the treatment of acute bacterial sinusitis or community-acquired pneumonia in adults.
For prophylaxis of disseminated MAC infections, azithromycin 1.2 g may be given once weekly. For treatment or secondary prophylaxis, 500 mg once daily should be given with other antimycobacterials.