(For the use only of a registered Medical Practitioner or a Hospital or a Laboratory)

AEROAZERO™ 500

Azithromycin Tablets USP

COMPOSITION: Each film coated Tablet contains :

Azithromycin USP	
Eq. to Anhydrous Azithromycin	500 mg
Excipients	q.s

Colour : Titanium Dioxide USP

1. DESCRIPTION:- Azithromycin is used to treat certain bacterial infections in many different parts of the body. This medicine may mask or delay the symptoms of syphilis. It is not effective against syphilis infections. Azithromycin belongs to the class of drugs known as macrolide antibiotics. It works by killing bacteria or preventing their growth. However, this medicine will not work for colds, flu, or other virus infections.This medicine is available only with your doctor's prescription.

2. INDICATION:- Acute bacterial sinusitis (adequately diagnosed),Acute bacterial otitis media (adequately diagnosed), Pharyngitis, tonsillitis, Acute exacerbation of chronic bronchitis (adequately diagnosed), Mild to moderately severe community acquired pneumonia, Infections of the skin and soft tissues of mild to moderate severity e.g. folliculitis, cellulitis, erysipelas, Uncomplicated Chlamydia trachomatis urethritis and cervicitis,Consideration should be given to official guidance on the appropriate use of antibacterial agents.

3. POSOLOGY AND METHOD OF ADMINISTRATION: - Posology:-Azithromycin tablets should be given as a single daily dose. The duration of treatment in each of the infectious diseases is given below.

Adults, elderly, children and adolescents over 45 kg body weight: - The total dosage of azithromycin is 1500 mg which is spread over three days (500 mg once daily). Alternatively, the dosage can be spread over five days (500 mg as a single dose on the first day and thereafter 250 mg once daily).

In uncomplicated *Chlamydia trachomatis* urethritis and cervicitis the dosage is 1000 mg as a single oral dose.For sinusitis, treatment is indicated for adults and adolescents 16 years of age and over.

Children and adolescents 45 kg and under body weight: - Tablets are not indicated for these patients. Other pharmaceutical forms of azithromycin, e.g. suspensions may be used.

Elderly: - No dose adjustments are required for elderly patients. Since elderly patients can be patients with ongoing proarrhythmic conditions a particular caution is recommended due to the risk of developing cardiac arrhythmia and torsades de pointes.

Method of administration:-For oral use.The tablets can be taken with or without food.

4. WARNING & PRECAUTIONS:-

Allergic reactions :-As with erythromycin and other macrolides, rare serious allergic reactions including angioneurotic oedema and anaphylaxis (rarely fatal) have been reported alongside dermatological reactions, including acute generalised exanthematous pustulosis (AGEP), Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) (rarely fatal) and DRESS syndrome (Drug Reaction with Eosinophilia and Systemic Symptoms). A certain number of these reactions resulted in recurring symptoms and required an extended period of observation and treatment.If an allergic reaction occurs, use of this medicinal product must be discontinued and the appropriate treatment initiated. Doctors must be aware that allergic symptoms can recur if symptomatic treatment is discontinued.

Renal impairment:- No dose adjustment is necessary in patients with mild to moderate renal impairment (creatinine clearance > 40 m/min).). In patients with severe renal function impairment (GFR < 10 mL/min), a 33% increase in systemic exposure to azithromycin has been observed.

Hepatic impairment:-Since liver is the principal route of elimination for azithromycin, the use of azithromycin should be undertaken with caution in patients with significant hepatic disease. Cases of fulminant hepatitis potentially leading to life-threatening liver failure have been reported with azithromycin (see section 4.8). Some patients may have, or have had pre-existing hepatic disease or may have been taking other hepatotoxic medicinal products.

5. CONTRAINDICATIONS: - Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.or to erythromycin or any macrolide or ketolide antibiotic.

6.UNDESIRABLE EFFECT:- Stomach upset, diarrhea/loose stools, nausea, vomiting, or abdominal pain may occur. If any of these effects persist or worsen, tell your doctor or pharmacist promptly.Remember that your doctor has prescribed this medication because he or she has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects. Tell your doctor right away if any of these unlikely but serious side effects occur: hearing changes (such as decreased hearing, deafness), eye problems (such as drooping eyelids, blurred vision), difficulty speaking/swallowing, muscle weakness, signs of liver problems (such as unusual tiredness, persistent nausea/vomiting, severe stomach/abdominal pain, yellowing eyes/skin, dark urine).Get medical help right away if any of these rare but seriousfast/irregular heartbeat, severe dizziness, fainting.

7. PHARMACODYNAMIC PROPERTIES: - Azithromycin is a macrolide antibiotic belonging to the azalide group. The molecule is constructed by adding a nitrogen atom to the lactone ring of erythromycin A. The chemical name of azithromycin is 9-deoxy-9a-aza-9a-methyl-9a-homo-erythromycin A. The molecular weight is 749.0.The action mechanism of azithromycin is based upon the suppression of bacterial protein synthesis, by binding to the 50 S subunit and thus inhibiting the translocation of peptides. Generally, the resistance of different bacterial species to macrolides has been reported to occur by three mechanisms associated with target site alteration, antibiotic modification, or altered antibiotic transport (efflux). The efflux in streptococci is conferred by the *mef* genes and results in a macrolide-restricted resistance (M phenotype). Target modification is controlled by *erm* encoded methylases.

8. PHARMACOKINETIC PROPERTIES:-

Absorption **:-** Following oral administration the bio-availability of azithromycin is approximately 37%. Peak plasma levels are reached after 2-3 hours. The mean maximum concentration observed (Cmax) after a single dose of 500 mg is approximately 0.4 μg/ml.

Distribution: - Orally administered azithromycin is widely distributed throughout the body. Pharmacokinetic studies have shown considerably higher azithromycin concentrations in the tissues (up to 50 times the maximum concentration observed in the plasma). This indicates that the substance is extensively bound in the tissues (steady-state volume of distribution approximately 31 l/kg). With the recommended dosage no accumulation in the serum/plasma occurs. Accumulation does occur in the tissues where the levels are much higher than in the serum/plasma. Concentrations in target tissues such as lung, tonsil, and prostate exceed the MIC90 for likely pathogens after a single dose of 500 mg. In experimental *in vitro* and *in vivo* studies, azithromycin accumulates in phagocytes; release is promoted by active phagocytosis. In animal models this process appears to contribute to the accumulation of azithromycin in tissue.The binding of azithromycin to plasma proteins is variable and varies from 52% at 0.005 μg/ml to 18% at 0.5 μg/ml.

Biotransformation and Excretion:-The terminal plasma elimination half-life follows the tissue depletion half-life of 2 to 4 days. Approximately 12% of an intravenously administered dose is excreted in unchanged form with the urine over a period of 3 days; the major proportion in the first 24 hours. Concentrations of up to 237 μg/ml azithromycin, 2 days after a 5-day course of treatment, have been found in human bile, together with 10 metabolites (formed by N- and O-demethylation, by hydroxylation of the desosamine and aglycone rings, and by splitting of the cladinose conjugate). Investigations suggests that the metabolites do not play a role in the micro-biological activity of azithromycin.

9. PREGNANCY AND LACTATION:- Pregnancy: There are no adequate data from use of azithromycin in pregnant women. In reproduction toxicity studies in animals, azithromycin was shown to pass the placenta, but no teratogenic effects were observed. The safety of azithromycin has not been confirmed with regard to the use of the active substance during pregnancy. Therefore, azithromycin should only be used during pregnancy if the benefit outweighs the risk.

Breast-feeding:- Azithromycin passes into human breast milk, but there are no adequate and well-controlled clinical studies in nursing women that have characterised the pharmacokinetics of azithromycin excretion into human breast milk. Because it is not known whether azithromycin may have adverse effects on the breast-fed infant, nursing should be discontinued during treatment with azithromycin. Among other things diarrhoea, fungus infection of the mucous membrane as well as sensitisation is possible in the nursed infant. It is recommended to discard the milk during treatment and up until 2 days after discontinuation of treatment. Nursing may be resumed thereafter.

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

11. HOW TO SUPPLIED:-10 x 3 tablets packed in blister pack.

Shelf Life: -Refer to carton and strip.

Storage: Store at controlled room temperature. Protect from light and moisture.

Keep all medicine out of reach of children.

Número de registro.:
Código neutral: HP/Drugs/09/92

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