

## **Unizithrin Suspension Powder for**

### **Composition:-**

Each 5 ml of Unizithrin suspension contains Azithromycin dihydrate equivalent to 100 mg Azithromycin base.

### **Indication:-**

Azithromycin is indicated for the treatment of patients with mild to moderate infections caused by susceptible strains of the designated microorganisms in the specific conditions listed below:

### **Children:**

**Acute otitis media** caused by *Haemophilus influenzae*, *Moraxella catarrhalis* or *Streptococcus pneumoniae* .

**Community-acquired pneumonia** due to *Chlamydia pneumoniae*, *Haemophilus influenzae*, *Mycoplasma pneumoniae* or *Streptococcus pneumoniae* in patients appropriate for oral therapy.

**Pharyngitis/tonsillitis** caused by *Streptococcus pyogenes* as an alternative to first-line therapy in individuals who cannot use first-line therapy.

### **Posology & Method of Administration:**

Unizithrin should be administered as a SINGLE daily dose.

Unizithrin powder for oral suspension form can be taken with food.

### **Dose and administrations:**

Unizithrin for oral suspension can be taken with or without food.

**Acute Otitis Media:** The recommended dose of Unizithrin for oral suspension for the treatment of children with acute otitis media is 30 mg/kg given as a single dose or 10 mg/kg once daily for 3 days or 10 mg/kg as a single dose on the first day followed by 5 mg/kg/day on Days 2 through 5.

**Community-Acquired Pneumonia:** The recommended dose of Unizithrin for oral suspension for the treatment of children with community-acquired pneumonia is 10 mg/kg as a single dose on the first day followed by 5 mg/kg on Days 2 through 5.

### **\*Instructions for use:**

**P.O.S.:**1- Add distilled water up to the mark, to get 30 ml of suspension.

2- Shake well prior each use.

### **\* Contraindications:**

Unizithrin is contraindicated in patients with known hypersensitivity to azithromycin, erythromycin or any macrolide antibiotic.

### **Warnings & Precautions:**

- As with other macrolides, rare serious allergic reactions e.g. angioedema and anaphylaxis have been reported.
- Caution should be exercised before prescribing Unizithrin to patients with severe renal impairment, as there are not enough data regarding Azithromycin usage in such cases.
- Also, caution should be exercised before prescribing Unizithrin to patients with significant hepatic disease, as liver is the principle elimination route for Azithromycin.
  - Azithromycin and ergot derivatives should not be co administered, because there is a theoretical possibility of ergotism.

**Side effect:-**

**In rarely cases:** Chest pain, Dyspepsia, constipation, anorexia, enteritis, flatulence, gastritis, jaundice, loose stools and oral moniliasis, Anemia and leukopenia, Headache (otitis media dosage), hyperkinesia, dizziness, agitation, nervousness and insomnia, Cough increased, pharyngitis, pleural effusion and rhinitis, Conjunctivitis.

**Drug – drug interaction:-**

Due to the possibility of drug - drug interaction between Unizithrin and other medicaments, caution should be exercised with patients receiving Unizithrin concomitantly with Antacids, Cyclosporine, Digoxin, Ergot derivatives

On the other hand, pharmacokinetic studies revealed that there is no evidence of interaction between Azithromycin and Cimetidine, Methylprednisolone, Theophylline; Terfenadine, Zidovudine. With warfarin, Zisrocin may be co-administered, but monitoring of the prothrombin time should be continued as routinely performed.

**Pharmacological properties:**

**- Pharmacodynamics**

Azithromycin is the first of a class of antibiotic designated chemically as azalides. Chemically it is derived by insertion of a nitrogen atom into the lactone ring of erythromycin A. The mode of action of azithromycin is inhibition of protein synthesis in bacteria and preventing translocation of peptides. In vitro, Azithromycin demonstrates activity against a wide range of bacteria including:

- Gram positive aerobic bacteria: Staphylococcus aureus, Streptococcus pyogenes (group A beta - haemolytic streptococci), Streptococcus pneumoniae, alpha - haemolytic Streptococci (Viridans group) and other Streptococci, and Corynebacterium; diphtheriae. Azithromycin demonstrates cross resistance with erythromycin resistant Gram - positive strains; including Streptococcus faecalis (enterococcus) and most strains of methicillin - resistant Staphylococci.
- Gram - negative aerobic bacteria: Haemophilus influenzae, Neisseria meningitidis, Haemophilus parainfluenzae, Moraxella catarrhalis, Acinetobacter species, Yersinia species, Vibrio cholerae Parahaemolyticus, Plesiomonas Shigelloides, Legionella pneumophila, Bordetella pertussis, Bordetella parapertussis, Shigella species, Pasteurella species.

Azithromycin activities are variable against E.coli, Salmonella enteritidis, Salmonella typhi, Enterobacter species, Aeromonas hydrophila and Klebsiella species, and susceptibility tests should be performed. There are some species which are usually

resistant to Azithromycin e.g. Proteus species, Serratia species, Morganella species and Pseudomonas aeruginosa 'Anaerobic bacteria: Bacteroides fragilis, Bacteroid species, Clostridium perfringens, Peptococcus ~ species and Peptostreptococcus species, Fusobacterium, necrophorum and Propionibacterium acnes.

Organisms of S.T.Ds. Azithromycin is active against Chlamydia trachomatis and also shows good activity against Treponema pallidum, Neisseria gonorrhoeae and Haemophilus ducreyi,

Borrelia burgdorferi (lyme disease agent), Chlamydia pneumoniae, ~ Toxoplasma gondii, Mycoplasma pneumoniae, Mycoplasma hominis, Ureaplasma urealyticum, pneumocystis carinii, Mycobacterium avium - intracellulare, Campylobacter species ~ and Listeria monocytogenes.

### **Pharmacokinetics**

Following oral administration in human, Azithromycin is widely distributed throughout the body, bioavailability is approximately 37%. Administration following a substantial meal reduces

bioavailability of capsules, but not the powder for oral suspension, by at least 50%. The time taken to peak plasma levels is 2 – 3 hours. Plasma terminal elimination half - life closely reflects the tissue depletion half - life of 2 - 4 days. Pharmacokinetic studies have shown markedly higher Azithromycin levels in tissue than in plasma (up to 50 times the maximum observed concentration in plasma) indicating that the drug is heavily tissue bound.

Concentration in target tissues, such as lung, tonsil and prostate exceed the (MIC 90) for likely pathogens after a single dose of ; 500 mg.

In animal studies, high Azithromycin concentration have been ; observed in phagocytes. In experimental models, higher concentrations of Azithromycin are released during active

Phagocytosis than from nonstimulated phagocytes. In animal models this results in high concentrations of Azithromycin being delivered to the site of infection.

### **Pack:-**

Suspension: bottle containing 600 mg Azithromycin powder for oral suspension 100 mg 15 ml.

**Store below 25°C, protect from light. Keep out of reach of children**

**Produced by UNI PHARMA**