

**MODULE -1**  
**ADMINISTRATIVE INFORMATION FOR**  
**ZITHROCARE 500 TABLETS**

**1.5.1 SUMMARY OF PRODUCT CHARECTERISTICS**

**1. NAME OF MEDICINAL PRODUCT**

Zithrocare 500 Tablets

**2. QUALITATIVE QUANTITATIVE FORMULA**

<u>ITEM</u>	<u>DRUG NAME</u>	<u>QTY. PER TABLET</u>	<u>STANDARD QUANTITY PER 1000 TABLETS</u>
<b>I.</b>	<b>Granulation:</b>		
1.	Azithromycin Anhydrous Use: Azithromycin Dihydrate USP	500 mg (556.947 mg)	556.947 g
2.	Dibasic Calcium Phosphate BP	70 mg	70.000 g
3.	Pregelatinized Starch USP	60 mg	60.000 g
4.	Maize Starch (Dried)	17.053 mg	17.053 g
5.	Purified Water BP	q.s.	Approx. 120.000 g
<b>II.</b>	<b>Lubrication</b>		
6.	Magnesium Stearate BP	20 mg	20.000 g
7.	Sodium Lauryl Sulphate BP	2.5 mg	2.5000 g
8.	Croscarmellose Sodium BP	20 mg*	20.000 g
<b>III.</b>	<b>Colour Coating</b>		
9.	Instacoat Sol IC-S-223, White	30.0 mg	30.000 g
10.	Isopropyl Alcohol BP	q.s.	Approx. 260.00 g
11.	Methylene Chloride	q.s.	Approx. 490.00 g
<b>IV.</b>	<b>Printing</b>		
12.	Printing Ink for tablets (Black)		q.s

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**3. PHARMACEUTICAL FORM**

Tablet

**4. CLINICAL PARTICULARS**

**4.1 Therapeutic indications**

1. Upper Respiratory Tract Infections
2. Otitis Media
3. Lower Respiratory Tract Infections
4. Skin and Soft Tissue Infections
5. Sexually Transmitted diseases, especially genital Chlamydia infections
6. Mycobacterium avium intracellular complex infections in AIDS
7. Other sensitive infections

**4.2 Posology and method of administration**

As directed by Physician

**4.3 Contraindications**

1. Hypersensitivity to Azithromycin or any of the macrolide antibiotics.
2. Co-administration with ergot derivatives.

**4.4 Special warnings and precautions for use**

None

**4.5 WARNING:**

Azithromycin is not recommended for Neonates, Pregnant & Lactating Mothers

**4.6 Effects on ability to drive and use machines**

None

**4.7 Overdose**

Do not exceed the recommended doses. In case of overdosage consult the physician immediately.

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**4.8 Interaction with other medicinal products and other forms of interactions**

Caution is advised, when using Azithromycin in conjunction with drugs like Carbamazepine, Corticosteroids, Cyclosporine, Digoxin, Ergot alkaloids, theophylline and Warfarin. Azithromycin should be taken at least one hour before or two hour after administration of food and antacid preparations.

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**5. Pharmacological properties**

**5.1 Pharmacodynamic properties**

**Mechanism of Action**

Azithromycin binds to the 50S subunit of the 70S bacterial ribosomes, and therefore inhibits RNA-dependent protein synthesis in bacterial cells.

Azithromycin, a semisynthetic antibiotic belonging to the macrolide subgroup of azalides, is used to treat STDs due to chlamydia and gonorrhea, community-acquired pneumonia, pelvic inflammatory disease, pediatric otitis media and pharyngitis, and *Mycobacterium avium* complex (MAC) in patients with advanced HIV disease. Similar in structure to erythromycin, azithromycin reaches higher intracellular concentrations than erythromycin, increasing its efficacy and duration of action.

**5.2 Pharmacokinetic properties**

**Absorption:**

Bioavailability is 37% following oral administration. Absorption is not affected by food. Azithromycin is extensively distributed in tissues with tissue concentrations reaching up to 50 times greater than plasma concentrations. Drug becomes concentrated within macrophages and polymorphonucleocytes giving it good activity against *Chlamydia trachomatis*.

**Distribution:**

31.1 L/kg

**Metabolism:**

Hepatic. In vitro and in vivo studies to assess the metabolism of azithromycin have not been performed.

**Elimination:**

Biliary excretion of azithromycin, predominantly as unchanged drug, is a major route of elimination

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**6. Pharmaceutical particulars**

**6.1 List of excipients**

Diabasic Calcium Phosphate  
Pregelatinised Starch  
Maize Starch (dried)  
Magnesium Stearate  
Sodium Lauryl Sulphate  
Crosscarmellose Cellulose  
Methylene chloride  
Isopropyl Alcohol

**BP: British Pharmacopoeia**

**USP-NF: United State Pharmacopoeia-National Formulary**

**MS: Meyer Specifications**

**6.2 Incompatibilities**

None

**6.3 Shelf life**

36 months

**6.4 Special precautions for storage**

Store below 30°C, at a dry place.

Protect from light.

Keep medicines out of reach of children