SUMMARY OF PRODUCTS CHARACTERISTICS

1.NAME OF THE FINISHED PHARMACEUTICAL PRODUCT :

1.1 Brand Name : **Azileb-500 Tablets**
1.2 Generic Name : **Azithromycin Tablets USP**
1.3 Strength : **500mg/ Tablets**
1.4 Pharmaceutical Form: **Oral Tablets**

2. QUALITATIVE & QUANTITATIVE COMPOSITION :

Each film-coated tablet contains:
Azithromycin USP (dihydrate)
eq. to Azithromycin (anhydrous) USP 500mg.
Colour: Titanium Dioxide BP

1.	Azithromycin (dihydrate) eq. to Azithromycin (anhydrous)
2.	Starch (Maize)
3.	Pregelatinised Starch
4.	Povidone (PVPK-30)
5.	Sod. Methyl Hydroxybenzoate (Sod. Methylparaben)
6.	Sod. Propyl Hydroxybenzoate (Sod. Propylparaben)
7.	Sodium Lauryl Sulfate
8.	Magnesium Stearate
9.	Colloidal Anhydrous Silica (Colloidal Silicon Dioxide)
10.	Sodium Starch Glycolate
11.	Isopropyl Alcohol
12.	Hypromellose (HPMC-15cps)
13.	Colour Titanium Dioxide (77891)
14.	Macrogol-4000 (P.E.G.- 4000)
15.	Diethyl Phthalate
16.	Purified Talc (Talcum)
17.	Dichloromethane (Methylene Chloride)
18.	Methanol

3. PHARMACEUTICAL FORM

Tablet Oral

White colored elongated biconvex film coated tablet having central break line on one face of each tablet.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Azileb-500 Tablet (Azithromycin Tablets) Prevention of secondary case of invasive group A streptococcal infection in patients who are allergic to penicillin, Respiratory-tract infections, otitis media, skin and soft- tissue infections, Lyme disease (under expert supervision), Mild to moderate typhoid due to multiple-antibacterial resistant organisms. Community-acquired pneumonia, low to moderate severity.

4.2 Posology and method of administration

Prevention of secondary case of invasive group A streptococcal infection in patients who are allergic to penicillin.

Child 6 months–11 years: 12 mg/kg once daily (max. per dose 500 mg) for 5 days
Child 12–17 years: 500 mg once daily for 5 days
Adult: 500 mg once daily for 5 days

Respiratory-tract infections, otitis media, skin and soft- tissue infections:

Child 6 months–17 years: 10 mg/kg once daily (max. per dose 500 mg) for 3 days
Child 6 months–17 years: (body-weight 15–25 kg): 200 mg once daily for 3 days
Child 6 months–17 years: (body-weight 26–35 kg): 300 mg once daily for 3 days
Child 6 months–17 years: (body-weight 36–45 kg): 400 mg once daily for 3 days
Child 6 months–17 years: (body-weight 46 kg and above): 500 mg once daily for 3 days
Adult: 500 mg once daily for 3 days, alternatively initially 500 mg once daily for 1 day, then 250 mg once daily for 4 days.

Lyme disease (under expert supervision):

Adult: 500 mg once daily for 7–10 days.

Mild to moderate typhoid due to multiple-antibacterial resistant organisms:

Adult: 500 mg once daily for 7 days.

Community-acquired pneumonia, low to moderate severity:

Adult: 500 mg once daily for 3 days, alternatively initially 500 mg once daily for 1 day, then 250 mg once daily for 4 days.

4.3 Contraindications

Azileb (Azithromycin) is contraindicated in patients with known hypersensitivity to azithromycin, erythromycin, any macrolide or ketolide antibiotic. It is also contraindicated in patients with a history of cholestatic jaundice/hepatic dysfunction associated with prior use of azithromycin.

4.4 Special warnings and special precautions for use

Macrolides should be used with caution during electrolyte disturbances (predisposition to QT interval prolongation) may aggravate myasthenia gravis .predisposition to QT interval prolongation.

4.5 Interaction with other FPPs and Other forms of Interaction

Antacids reduce absorption of Azithromycin, possible increased risk of colchicine toxicity when given with Azithromycin, anticoagulant effect of coumarins possibly enhanced by Azithromycin, Azithromycin possibly increases plasma concentration of disopyramide, separating administration from azithromycin and isoniazid by 12 hours; increased risk of side-effects including neutropenia when azithromycin given with rifabutin, plasma concentration of azithromycin and erythromycin possibly increased by ritonavir.

4.6 Pregnancy and lactation

Advise to use Azithromycin during pregnancy only if adequate alternatives are not available. Azithromycin may be present in breast feeding mother's milk; use only if no suitable alternatives.

4.7 Effects on ability to drive and use machines

There are no data available about the influence of azithromycin on the ability to drive or operate machines. However azithromycin tablets may cause dizziness and seizures so make sure you are not affected before driving or operating machinery.

4.8 Undesirable effects

Common or very common: Anorexia, arthralgia, disturbances in taste, disturbances in vision, dizziness, dyspepsia, flatulence, headache, malaise, paraesthesia, reversible hearing loss (sometimes with tinnitus) after long-term therapy.

Uncommon anxiety: Chest pain, constipation, gastritis, hypoaesthesia, leucopenia, oedema, photosensitivity, sleep disturbances. **Rare:** Agitation. Frequency not known : Acute renal failure: convulsions, haemolytic anaemia, interstitial nephritis, smell disturbances, syncope, thrombocytopenia, tongue, discoloration.

4.9 Overdose

Overdose symptoms may include nausea, vomiting, diarrhea, and stomach discomfort. For treatment seek emergency medical attention.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties:

Pharmacotherapeutic group:

ATC Code: J01FA10

Mechanism of action:

Azithromycin works by decreasing the production of protein, thus stopping bacterial growth. Its effects may be bacteriostatic or bactericidal depending of the organism and the drug concentration.

5.2 Pharmacokinetic properties

Plasma concentrations of Azithromycin is very low but tissue concentrations are much higher. It has a long tissue half-life and once daily dosage is recommended. Bioavailability of Azithromycin is approximately 37% following oral administration. Absorption is not affected by food. Serum protein binding is variable in the concentration range

approximating human exposure. Biliary excretion of azithromycin, predominantly as unchanged drug, is a major route of elimination.

5.3 Preclinical safety data

None Known

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Starch (Maize)	BP
Pregelatinised Starch	BP
Povidone (PVPK-30)	BP
Sod. Methyl Hydroxybenzoate (Sod. Methylparaben)	BP
Sod. Propyl Hydroxybenzoate (Sod. Propylparaben)	BP
Sodium Lauryl Sulfate	BP
Magnesium Stearate	BP
Colloidal Anhydrous Silica (Colloidal Silicon Dioxide)	BP
Sodium Starch Glycolate	BP
Isopropyl Alcohol	BP
Coating : (Film Coating)	
Hypromellose (HPMC-15cps)	BP
Colour Titanium Dioxide (77891)	BP
Macrogol-4000 (P.E.G.- 4000)	BP
Diethyl Phthalate	BP
Purified Talc (Talcum)	BP
Dichloromethane (Methylene Chloride)	BP
Methanol	BP

6.2 Incompatibilities

Not sufficient data available

6.3 Shelf life

24month from the date of manufacturing.

6.4 Special precautions for storage

Store at a temperature not exceeding 30°C. Protect from light. Keep away from moisture. Keep out of reach of Children.

6.5 Nature and contents of container

1 blister of 3 tablets packed in a mono pack.

6.6 Instructions for use and handling

Please see the package insert.

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESS

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8. MARKETING AUTHORISATION NUMBER

04480/06838/REN/2018

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Oct 10, 2019

10. DATE OF REVISION OF THE TEXT

Oct 10, 2019