SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICALPRODUCT :

1.1 Brand Name : **Azileb-200 Suspension**
1.2 Generic Name : **Azithromycin Oral Suspension**
1.3 Strength : **Azithromycin 200mg per 5ml**
1.4 Pharmaceutical Form: **Suspension**

2. QUALITATIVE & QUANTITATIVE COMPOSITION :

Each 5ml contains:
Azithromycin USP (dihydrate)
eq. to Azithromycin (anhydrous) USP 200 mg
Flavoured syrupy base q.s.
Colour: Quinoline Yellow WS.

3. PHARMACEUTICAL FORM

Oral Suspension
Yellow colored flavored palatable suspension

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Azileb(Azithromycin) is indicated for treatment of secondary case of invasive group A streptococcal infection in patients who are allergic to penicillin, Lyme disease, 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 & 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: 500mg once daily 3days, alternatively initially 500mg once daily 1 day, then 250mg once daily 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 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.

INSTRUCTION FOR USE:

Take this medicine by mouth only. Do not take more than recommended dosage.
SHAKE WELL BEORE USE.

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 colchicines 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 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: Macrolide Antibacterial**.**

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.

5.3 Preclinical safety data

None Known

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ionex QM-1011	IH
Sorbitol Solution 70%	BP
Sucrose	BP
Sodium Methylparaben	BP
Sodium Propylparaben	BP
Aspartame	BP
Ammonium Glycyrrhizinate	IH
Sodium Citrate	BP
Xanthan Gum	BP
Polysorbate-80	BP
Essence Peppermint C7531	IH
Essence Mango Flavour S3212	IH
Essence Licorice 9254	IH
Col. Quinoline Yellow WS 47005	IH
Purified Water	BP

6.2 Incompatibilities

Not sufficient data available

6.3 Shelf life

24 month 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

15 ml & 30ml in an amber colour PET bottle in an inner carton.

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

07957/06992/NMR/2018

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorization: Oct 21, 2022

10. DATE OF REVISION OF THE TEXT

01/01/2023