

1. NAME OF THE MEDICINAL PRODUCT:

Azicip-500

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each film-coated tablet contains

Aztreonam (Aztreonam Hydrochloride USP) ... 500 mg

(As Aztreonam Hydrochloride USP)

3. PHARMACEUTICAL FORM:

Tablets

4. CLINICAL PARTICULARS:

4.1 Therapeutic indications:

Aztreonam is a macrocyclic antimicrobial drug 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. Results of clinical trials and durations of therapy in adult and pediatric patient populations vary in these indications (see section 4.2)

• Acute bacterial exacerbations of chronic bronchitis due to *Haemophilus influenzae*, *Moraxella catarrhalis*, or *Streptococcus pneumoniae*.

• Acute bacterial exacerbations of chronic bronchitis due to *Haemophilus influenzae*, *Moraxella catarrhalis*, *Streptococcus pneumoniae* or *Streptococcus pyogenes* as an alternative to first-line therapy in individuals who cannot use first-line therapy.

• Uncomplicated skin and skin structure infections due to *Staphylococcus aureus*, *Streptococcus pyogenes*, or *Escherichia coli*.

• Urethritis and cervicitis due to *Chlamydia trachomatis* or *Neisseria gonorrhoeae*.

• Genital ulcer disease in men due to *Haemophilus ducreyi* (chancroid). Due to the small number of women included in these trials, the efficacy of aztreonam in the treatment of chancroid in women has not been established.

Limitations of Use

Administration should not be used in patients with preferences who are judged to be inappropriate for oral therapy because of moderate to severe risk of rashes as any of the following:

• patients with cyclic thrombopenia

• patients with recurrent mucocutaneous infections

• patients with known or suspected bacteremia

• patients requiring hospitalization

• elderly patients, especially patients with renal impairment

• patients with significant underlying health problems that may compromise their ability to respond to their illness (including immunodeficiency or functional asplenia).

Usage:

Not recommended for use in patients with preferences who are judged to be inappropriate for oral therapy because of the development of moderate to severe rashes as any of the following: aztreonam and other antimicrobial drugs, aztreonam should be used only for those infections that are proven or strongly suspected to be caused by these microorganisms. When culture and susceptibility information are available, they should be considered in selecting or modifying antimicrobial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empirical selection of therapy.

4.2 **Pharmacology and mode of administration:**

(see sections 4.1 and 4.2)

Infection* Recommended Dose/Duration of Therapy

Community-acquired pneumonia Pharyngitis/ Tonsillitis/ Otitis media/ Urticaria/ Skin/soft tissue (uncomplicated)

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