SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

ZIMYCIN 500
Azithromycin 500 mg Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film coated tablet contains:
Azithromycin Dihydrate USP
Eq.to Azithromycin : 500 mg
Excipients : Q.S.
Colour : Erythrosine
For excipients, see 6.1.

3. PHARMACEUTICAL FORM

Tablet
For oral administration

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

ZIMYCIN 500 is indicated for treatment of mild to moderate infections caused by susceptible strains of the designated microorganisms in the following diseases and specific conditions. As recommended dosages, durations of therapy, and applicable patient populations vary among these infections;

Adults

- **Infections of the upper respiratory tract: Pharyngitis and Tonsillitis**

Pharyngitis and tonsillitis caused by Streptococcus pyogenes (group A β-hemolytic streptococci) occurring in individuals who cannot use first line therapy.

- **Acute Bacterial Exacerbations of Chronic Obstructive Pulmonary Disease**

Acute bacterial exacerbations of chronic obstructive pulmonary diseases caused by Hæmophilus influenzæ, Moraxella catarrhalis, or Streptococcus pneumoniæ.

- **Community-Acquired Pneumonia**

Community-acquired pneumonia caused by Streptococcus pneumoniæ, Hæmophilus influenzæ, Mycoplasma pneumoniæ or Chlamydia pneumoniæ in patients for whom oral therapy is appropriate.

- **Uncomplicated Skin and Skin Structure Infections**

Uncomplicated skin and skin structure infections caused by Staphylococcus aureus, Streptococcus pyogenes or Streptococcus agalactiæ.

- **Genitourinary Tract Infections**

Urethritis and cervicitis due to Neisseria gonorrhoeæ or Chlamydia trachomatis. Genital ulcer disease in men due to Hæmophilus ducreyi (chancroid). Due to the small number of women included in clinical trials, the efficacy of azithromycin in the treatment of chancroid in women has not been established.

Pediatrics

- **Acute otitis media**

Acute otitis media caused by Haemophilus influenzae (β-lactamase positive and negative strains), Moraxella catarrhalis or Streptococcus pneumoniae.

- **Pharyngitis and tonsillitis**

Pharyngitis and tonsillitis caused by Streptococcus pyogenes (group A β-hemolytic streptococci) occurring in individuals who cannot use first line therapy.

- **Community-acquired pneumonia**

Community-acquired pneumonia caused by Haemophilus influenzae, Streptococcus pneumoniae, Mycoplasma pneumoniae or Chlamydia pneumoniae in patients for whom oral therapy is appropriate.

4.2 Posology and method of administration

Children and adolescents with a body weight above 45 kg, adults and the elderly:
The total dosage of azithromycin is 1500 mg, staggered over three days (500 mg once daily). Alternatively, the dosage may be staggered over five days (500 mg as a single dose on the first day, and then 250 mg once daily).
In the case of uncomplicated Chlamydia trachomatis urethritis and cervicitis, the dosage is 1000 mg as a single oral dose.

Children and adolescents with a body weight below 45 kg:
Tablets are not indicated for these patients. Other pharmaceutical forms of azithromycin may be used, such as suspensions.

Elderly patients:
The same dosage as in adult patients is used in the elderly. Since elderly patients can be patients with ongoing proarrhythmic conditions a particular caution is recommended due to the risk of developing cardiac arrhythmia and torsades de pointes.

Hepatic Impairment
Dose adjustment is not required for patients with mild to moderate hepatic dysfunction.

Renal Impairment

Dose adjustment is not required in patients with mild to moderate renal impairment (GFR 10-80 ml/min).

4.3 Contraindications

ZIMYCIN 500 contraindicated in patients with a history of cholestatic jaundice/hepatic dysfunction associated with prior use of azithromycin and in those with hypersensitivity to azithromycin, erythromycin, any macrolide or ketolide antibacterial agent, or to any ingredient in the formulation or component of the container.

4.4 Special warnings and precautions for use

Azithromycin should be used with caution in patients with illness or any allergy, especially allergies to drugs, liver disease, jaundice, history of colitis or stomach problems or kidney disease. This drug should be used only if clearly needed during pregnancy or lactation.

4.5 Interaction with other medicinal products and other forms of interaction

Using azithromycin with any of the following medicines is not recommended. Your doctor may decide not to treat you with this medication or change some of the other medicines you take.
Dihydroergotamine, Dronedarone, Ergoloid Mesylates, Ergonovine, Ergotamine, Methylergonovine, Methysergide, Pimozide
Using azithromycin with any of the following medicines is usually not recommended, but may be required in some cases. If both medicines are prescribed together, your doctor may change the dose or how often you use one or both of the medicines.
Acecainide, Amiodarone, Azimilide, Bretylium, Disopyramide, Dofetilide, Ibutilide, Propafenone, Sematilide, Sotalol, Tedisamil.
Using azithromycin with any of the following medicines may cause an increased risk of certain side effects, but using both drugs may be the best treatment for you. If both medicines are prescribed together, your doctor may change the dose or how often you use one or both of the medicines.
Atorvastatin, Digoxin, Fentanyl, Lovastatin, Nelfinavir, Rifabutin, Simvastatin, Theophylline, Warfarin.

4.6 Pregnancy and lactation

Pregnancy
There are no adequate studies in pregnant women studies have shown an adverse effect, but adequate studies in pregnant women have failed to demonstrate a risk to the fetus.
Lactation:
Azithromycin has been reported to be secreted into human breast milk, but there are no adequate and well-controlled clinical studies in nursing women that have characterized the pharmacokinetics of azithromycin excretion into human breast milk.

A risk to the suckling infant cannot be excluded. Azithromycin should not be used in the treatment of a lactating woman unless the potential benefits justify the potential risks to the infant.

4.7 Effects on ability to drive and use machines

Azithromycin can make you feel dizzy. If this happens to you, do not drive, ride a bike or operate machinery until the dizziness stops. It's an offence to drive a car if your ability to drive safely is affected.

4.8 Undesirable effects

- Diarrhoea;
- Difficulty breathing or swallowing;
- Hives;
- Hoarseness;
- Itching;
- Mild skin rash;
- Rapid, pounding, or irregular heartbeat;
- Severe skin rash;
- Stomach pain;
- Swelling of the face, throat, tongue, lips, eyes, hands, feet, ankles, or lower legs;
- Upset stomach;
- Vomiting;
- Yellowing of the skin or eyes;

4.9 Overdose

Adverse events experienced in higher than recommended doses were similar to those seen at normal doses. In the event of overdosage, general symptomatic and supportive measures are indicated as required.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antibacterials for systemic use, macrolides
ATC code: J01FA10
Azithromycin, an azolide, is a subclass of the macrolide antibiotics. It is derived from erythromycin, but its chemical structure differs slightly by having a methyl-substituted nitrogen atom in the lactone ring. Azithromycin has the ability to block protein synthesis.
This drug is primarily bacteriostatic, but can be bactericidal depending on the concentration given. It is effective against aerobic Gram-positive microorganisms, and some Gram-negative

organisms. However, azithromycin does not appear to have any inherent direct activity against Pseudomonas aeruginosa (a Gram-negative, rod-shaped, opportunistic pathogen).

5.2 Pharmacokinetic properties

No data exist in humans in regard to the extent of accumulation, duration of exposure, metabolism or excretory mechanisms of azithromycin in neural tissue such as the retina and the cochlea.

Adult Pharmacokinetics
Plasma concentrations of azithromycin decline in a polyphasic pattern, resulting in an average terminal half-life of 68 hours. The prolonged half-life is likely due to extensive uptake and subsequent release of drug from tissues. Over the dose range of 250 to 1000 mg orally, the serum concentrations are related to dose.
Azithromycin is absorbed both widely and rapidly throughout the body. When distributed in the body, concentrations are found to be greater in tissue compared to that of plasma and serum levels. Due to azithromycin's high oral bioavailability, long half-life, and ability to attain high tissue concentrations, it lends itself to a once daily dosing regimen.
The drug undergoes some hepatic (liver) metabolism, with the majority of the drug being excreted in bile, and to a lesser extent in urine.

5.3 Preclinical Safety Data

In animal studies using exposures 40 times those achieved at the clinical therapeutic dosages, azithromycin was found to have caused reversible phospholipidosis, but as a rule there were no associated toxicological consequences. The relevance of this finding to humans receiving azithromycin in accordance with the recommendations is unknown.
Electrophysiological investigations have shown that azithromycin prolongs the QT interval.

Carcinogenic potential:
Long-term studies in animals have not been performed to evaluate carcinogenic potential.
Mutagenic potential:
There was no evidence of a potential for genetic and chromosome mutations in in-vivo and in-vitro test models.
Reproductive toxicity:
Teratogenic effects were not observed in rat reproductive toxicity studies. At slight maternally toxic doses retardation in foetal ossification was seen. In peri- and postnatal studies in rats mild retardations in physical and reflex development were noted.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Name of Material	Specification

Lactose	BP
Maize Starch	BP
Colloidal Anhydrous Silica	BP
Povidone	BP
Purified water	BP
Magnesium stearate	BP
Purified Talc	BP
Croscarmellose sodium	BP
Film coat erythrosine	IHS

6.2 Incompatibilities

NA

6.3 Shelf life

24 Months

6.4 Special precautions for storage

Store below 30°C. Protected from light.
KEEP OUT OF REACH OF CHILDREN

6.5 Nature and contents of container

1 x 3 Tablets in Alu-PVC pack is packed in a printed carton along with a package insert.

6.6 Instructions for use and handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER

SAGA
LIFESCIENCES LIMITED

Ahmedabad
Gujarat, India.
E-mail: info@sagalabs.com
URL: www.sagalabs.com

8. NUMBER(S) IN THE NATIONAL REGISTER OF FINISHED PHARMACEUTICAL PRODUCTS

08541/09352/NMR/2021

9. DATE OF FIRSHT AUTHORISATION/RENEWAL OF THE AUTHORISATION

05/04/2023

10. DATE OF REVISION OF THE TEXT

01 April 2026