# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. Name of Finished Pharmaceutical Product:

AZIAGIO 500 (Azithromycin Tablets USP)

Strength: 500 mg

Pharmaceutical Form: Film Coated Tablet

## 2. Qualitative and quantitative composition

AZIAGIO 500 (Azithromycin Tablets USP)

Each film-coated tablet contains:

Azithromycin USP (As dihydrate) equivalent to Azithromycin (anhydrous) - 500 mg; Colour: Lake Ponceau 4R & Titanium Dioxide B.P

Exipients ..... q.s.

## 3. Pharmaceutical Form:

Film Coated Tablet

Visual Description: Description: Pink coloured capsule shaped biconvex film coated tablet, plain on both sides.

## 4. Clinical Particulars

### 4.1 Therapeutic indications

Infectious and inflammatory diseases caused by microorganisms sensitive to the drug: -

- Tonsillitis, Pharyngitis, Sinusitis, Otitis media; -
- Chronic bronchitis, Community acquired pneumonia or Hospital acquired pneumonia;
- Erysipelas, Impetigo, Secondarily infected dermatoses; - Lyme disease (for the treatment of the initial stage);
- Diseases of the stomach and duodenum associated with Helicobacter pylori (as part of combination therapy); - Sexually transmitted diseases (including urethritis, cervicitis, genital and extra genital chlamydia).

### 4.2 Posology and Method of Administration

For oral administration.

Adults:

With infections of the upper and lower respiratory tract; for infections of the skin and soft

tissues: 500 mg / day for 3 days.

In Lyme disease for the treatment of the initial stage: 1 gm on the first day and 500 mg / day

with 2 to 5 days.

In diseases of the stomach and duodenum associated with Helicobacter pylori: 1000 mg / day

for 3 days as part of combination therapy.

For sexually transmitted diseases: uncomplicated urethritis / cervicitis - once 1000 mg.

Children 12 years and older:

500 mg tablets to children aged 12 years and older weighing more than 45 kg once /day for 3

days or first day at 10 mg / kg of body weight, then 5-10 mg / kg of body weight per day for 3

days. With a body weight of less than 45 kg, another dosage form should be taken.

In the treatment of the first stage of Lyme disease: the dose is 20 mg / kg body weight on the

first day and 10 mg / kg body weight from 2 to 5 days.

If you miss one dose of the drug, you should take the missed dose as soon as possible, and

subsequent doses should be taken at intervals of 24 hours.

In the elderly and in patients with impaired renal function, there is no need to change the

dosage.

Azithromycin tablets 500 mg can be administered with or without food. The tablet should be

swallowed whole with water or, as prescribed by the physician.

Method of Administration

Oral

## 4.3 Contraindications

In patients with known hypersensitivity to azithromycin or to any other macrolide / ketolide

class of drug or to any component of the formulation.

In patients with a history of cholestatic jaundice or hepatic dysfunction associated with prior

use of azithromycin.

## 4.4 Special warning and precautions for use

Exercise caution when prescribing the drug to patients with insufficiency of liver and kidney function. Abnormal liver function, hepatitis, cholestatic jaundice, hepatic necrosis, and hepatic failure have been reported, some of which have resulted in death. Discontinue azithromycin immediately if signs and symptoms of hepatitis occur.

It is necessary to observe a break of 2 hours with the simultaneous use of antacids.

QT Prolongation / Cardiovascular Events: Prolonged cardiac repolarization and QT interval, imparting a risk of developing cardiac arrhythmia and torsades de pointes, have been seen during treatment with other macrolides. A similar effect with azithromycin cannot be completely ruled out in patients at increased risk for prolonged cardiac repolarization.

Therefore, as the following situations may lead to an increased risk for ventricular arrhythmias (including torsade de pointes) which can lead to cardiac arrest, azithromycin should be used with caution in patients with on going pro-arrhythmic conditions (especially women and elderly patients) such as patients:

With congenital or documented QT prolongation.Currently receiving treatment with other active substance known to prolong QT interval

such as antiarrhythmics of Class IA (quinidine and procainamide) and Class III (dofetilide, amiodarone and sotalol), cisapride, and terfenadine.

With electrolyte disturbance, particularly in case of hypokalaemia and

hypomagnesemia.

With clinically relevant bradycardia, cardiac arrhythmia or severe cardiac

insufficiency.

Clostridium Difficile-Associated Diarrhea (CDAD): Clostridium difficile-associated diarrhea has been reported with use of nearly all antibacterial agents, including azithromycin, and may range in severity from mild

diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon, leading to overgrowth of C. difficile. Clostridium difficile produces toxins A and B which contribute to the development of CDAD. CDAD must be considered in all patients who present with diarrhea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over 2 months after the administration of antibacterial agents. If CDAD is suspected or confirmed, ongoing antibiotic

use not directed against C. difficile may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of C. difficile, and surgical evaluation should be instituted as clinically indicated. Exacerbation of Myasthenia

Gravis: Exacerbation of symptoms of myasthenia gravis and new onset of myasthenic syndrome has been reported in patients receiving azithromycin therapy.

Use in Sexually Transmitted Infections: Azithromycin, at the recommended dose, should not be relied upon to treat syphilis. Antibacterial agents used to treat non-gonococcal urethritis may mask or delay the symptoms of incubating syphilis. All patients with sexually transmitted urethritis or cervicitis should have appropriate testing at the time of diagnosis; appropriate antibacterial therapy and follow-up tests should be initiated if infection is confirmed. Antibiotic Resistance: Prescribing azithromycin in the absence of a proven bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug resistant bacteria.

Intolerance to Carbohydrates/Sugar: Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take azithromycin.

Ergot Derivatives: In patients receiving ergot derivatives, ergotism has been precipitated by coadministration of some macrolide antibiotics. There are no data concerning the possibility of an interaction between ergot and azithromycin. However, because of the theoretical possibility of ergotism, azithromycin and ergot derivatives should not be co-administrated. Streptococcal Infections (Pharyngitis/Tonsillitis): Penicillin is usually the first choice for treatment of pharyngitis/tonsillitis due to Streptococcus pyogenes. Azithromycin is also effective against streptococcus, but can be used as an alternative to first-line therapy in individuals who cannot use first-line therapy.

After discontinuation of treatment, hypersensitivity reactions may persist in some patients, which requires specific therapy under medical supervision. Adverse effects such as visual impairment and blurred vision may have an effect on a patient's ability to drive or operate machinery. If affected, patient should not drive a vehicle or operating machines.

## 4.5 Interactions with other medicinal products and other forms of interactions

Antacids (aluminum and magnesium-containing), ethanol and food slow down and reduce the absorption of Azithromycin Tablets 500 mg.

With the joint appointment of warfarin and Azithromycin Tablets 500 mg (at usual doses), no changes in prothrombin time were detected, however, given that the interaction of macrolides and warfarin may increase the anticoagulant effect, patients need careful monitoring of prothrombin time.

Digoxin: Azithromycin Tablets 500 mg increases the concentration of digoxin. Ergotamine and dihydroergotamine: increased toxic effect (vasospasm, dysesthesia). Triazolam: Azithromycin Tablets 500 mg causes a decrease in clearance and an increase in the pharmacological action of triazolane.

Azithromycin Tablets 500 mg slows down the excretion and increases the plasma concentration and toxicity of cycloserine, indirect anticoagulants, methylprednisolone, felodipine, as well as drugs undergoing microsomal oxidation (carbamazepine, terfenadine, cyclosporine, hexobarbital, ergot alkaloids, valproic acid, disopyramide, bromocriptine, phenytoin, oral hypoglycemic agents, theophylline and other xanthine derivatives) - due to inhibition of microsomal oxidation in hepatocytes.

Lincosamines weaken the effectiveness of Azithromycin Tablets 500 mg, tetracycline and c

hloramphenicol increase it.

## 4.6 Fertility, pregnancy, and lactation

### Pregnancy

Pregnant Women Pregnancy Category B. In animal studies, no evidence of harm to the fetus due to azithromycin was found. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, azithromycin should be used during pregnancy only if clearly needed.

### Lactation

Lactating Women Azithromycin has been reported to be excreted in human breast milk in small amounts. Thus, caution should be exercised when azithromycin is administered to a nursing woman. Generally, azithromycin should not be used unless the physician feels that the potential benefits justify the possible risks to the infant.

### Paediatric

Paediatric Patients Safety and effectiveness of azithromycin has not been established in infants below 6 months old. Azithromycin Tablets 500 mg Tablets are not suitable for use in children as there is no dosage feasibility with these formulations. However, children above 6 months of age can use other paediatric formulations of azithromycin such as suspension and dispersible tablets.

**Elderly**

Geriatric Patients Elderly patients may be given the same dose as recommended for adults. No overall differences in safety or effectiveness were observed between elderly and younger subjects, and other reported clinical experience has not identified differences in response. between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out. Since elderly patients can be patients with on-going proarrhythmic conditions, a particular caution is recommended due to the risk of developing cardiac arrhythmia and torsades de pointes.

**Hepatic Impairment**

Patients Since azithromycin is metabolised in the liver and excreted in the bile, the drug should not be given to patients suffering from severe liver disease. No studies have been conducted regarding treatment of such patients with azithromycin.

**4.7 Effects on ability to drive and use machine**

No data are available regarding the influence of azithromycin on a patient's ability to drive or operate machinery. However, the possibility of undesirable effects like dizziness and convulsions should be taken into account when performing these activities. Visual impairment and vision blurred may have an effect on a patient's ability to drive or operate machinery.

**4.8 Undesirable Effects**

- Loss of appetite, anorexia, nausea, vomiting, discomfort in the abdomen (pain, cramps), flatulence, diarrhea, dyspepsia, melena, constipation; -
- Stomatitis, gingivitis, gastritis;
- Cholestatic jaundice, hepatitis;
- Reversible moderate increase in the activity of liver enzymes;
- Chest pain, palpitations, arrhythmias;
- Dizziness, headache, drowsiness, headache in children (during the treatment of otitis media), hyperkinesia, anxiety, neurosis, sleep disturbances, increased fatigue; -
- Neutrophilia and eosinophilia (disappear 2-3 weeks after stopping treatment) –
- Vaginal candidiasis; -
- Interstitial nephritis, acute renal failure; -

- Allergic reactions: itching, urticaria, rash, conjunctivitis, sensitivity reactions, angioedema and anaphylactic reactions.

  Serious allergic reactions, including angioedema, anaphylaxis, and dermatologic reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, and Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) have been reported rarely.

  Reporting of suspected adverse reactions:
  Healthcare professionals are requested to report any suspected adverse reactions via Pharmacy and the Poisons Board, Pharmacovigilance Electronic Reporting System
  (PvERS) https://pv.pharmacyboardkenya.org

### 4.9 Overdose

Adverse events experienced in higher than recommended doses were similar to those seen at normal doses. The typical symptoms of an overdose with macrolide antibiotics include reversible loss of hearing, severe nausea, vomiting and diarrhoea. In the event of overdose, the administration of medicinal charcoal and general symptomatic treatment and supportive measures are indicated as required.

## 5. Pharmacological Properties

Pharmacotherapeutic Group: Antimicrobials for systemic use. Macrolides

Code ATC: J01FA10

### 5.1 Mechanism of Action/ Pharmacodynamic Properties

Azithromycin Tablets 500 mg is a representative of a subgroup of macrolide antibiotics - azalides, has a wide spectrum of antibacterial action. By binding to the 50S subunit of ribosomes, it inhibits protein synthesis in the microbial cell.
Azithromycin is active against a number of:

- Gram-positive microorganisms: Streptococcus pneumoniae, Str. pyrogenes, Str. agalactiae, streptococci of groups C, F and G, Streptococcus aureus, Str. epidermidis, Corynebacterium diphtheriae.
- Gram-negative microorganisms: Naemophilus influenza, H. parainfluenzae and H. ducrevi, Moraxella catarrhalis, Bordetella pertussis and B. parapertussis, Neisseria gonorrhoeae and N. meningitidis, Brucella melitensis, Helicobacter pylori, Gardnerella vaginalis.
- anaerobic microorganisms: Clostridium spp., Peptostreptococcus spp. and Peptococcus spp.

- intracellular and other microorganisms: Legionella pneumophila, Chlamydia trachomatis and

C. pneumoniae, Mycoplasma pneumoniae, Mycoplasma hominis, Mycoplasma avium, Ureaplasma urealyticum, Lysteria monocytogenes, Treponema pallidum, Borrelia burgdorferi, Toxoplasma gondii.
Cross-resistance to azithromycin with erythromycin-resistant Gram-positive strains has been noted. Most strains of Enterococcus faecalis and methicillin-resistant staphylococci are resistant to azithromycin.
Azithromycin is inactive against Gram-positive bacteria resistant to erythromycin.

After oral administration, absorption occurs quickly and completely. Eating significantly reduces the degree (up to 50%) and the rate of absorption and therefore azithromycin should be taken one hour before a meal or 2 hours after that. The time to reach maximum plasma concentrations is 2-3 hours.

The distribution is intense as a result of the high degree of tissue penetration, which provides a much higher concentration in tissues than in plasma (up to 50 times). Azithromycin quickly penetrates into phagocytes and fibroblast cells and creates high intracellular and extracellular
Azithromycin is inactive against Gram-positive bacteria resistant to erythromycin.

## 5.2 Pharmacokinetic properties

After oral administration, absorption occurs quickly and completely. Eating significantly reduces the degree (up to 50%) and the rate of absorption and therefore azithromycin should be taken one hour before a meal or 2 hours after that. The time to reach maximum plasma concentrations is 2-3 hours.

The distribution is intense as a result of the high degree of tissue penetration, which provides a much higher concentration in tissues than in plasma (up to 50 times). Azithromycin quickly penetrates into phagocytes and fibroblast cells and creates high intracellular and extracellular concentrations. Its intraphagocytic concentration remains high after the depletion of extracellular concentrations. In the presence of bacteria in inflamed tissues, azithromycin quickly penetrates into the extracellular space. The degree of binding to plasma proteins is about 20%. Metabolism is carried out in the liver through demethylation. The half-life is 48 - 96 hours.

Excretion

The main route of excretion is with bile. Approximately 50% is excreted unchanged, the other 50% is in the form of inactive metabolites. Approximately 6% of the dose taken is excreted by the kidneys.

### 5.3 Preclinical Safety Data

No relevant information.

## 6. Pharmaceutical Particulars

### 6.1 List of Excipients

- Microcrystalline Cellulose
- Croscarmellose Sodium
- Sodium Lauryl Sulphate
- Colloidal Anhydrous Silica
- Maize Starch
- Povidone (PVP K-30)
- Microcrystalline Cellulose (PH 102)
- Purified Talc
- Magnesium Stearate
- Instacoat Universal Red IC-U-7146
- Purified Water

### 6.2 Incompatibilities

None known

### 6.3 Shelf Life

36 months

### 6.4 Special Precautions for Storage:

Store below 30°C in a dry place

### 6.5 Nature and Contents of Container:

3 tablets in a blister, 1 blister in a carton along with pack inserts.

**6.6 Special Precautions for Disposal and Other Handling**

**None**

**7. Marketing Authorisation Holder and Manufacturing Site Addresses**

**Marketing Authorisation Holder:**

Agio Pharmaceuticals Limited
A-38, Nandjyot Industrial Estate,
Kurla-Andheri Road, Safed Pool,
Andheri – East, Mumbai City,
Maharashtra, 400072, India.

**Manufacturing Site Address:**

At: T-81, 82, M.I.D.C.,
Bhosari, Pune 411026,
Maharashtra State,
India

**8. Marketing Authorisation Number**

H2009/19116/441

**9. Date of First Registration**

30/01/2026

**10. Date of Revision of Text**

27/02/2026