

**1.3 Summary of product characteristics, labelling and package leaflet.**

**1.3.1 Summary of product characteristics (SPC)**

**AFITHRO-500**  
Azithromycin Tablets

**1. NAME OF THE MEDICINAL PRODUCT**

AFITHRO-500 Film-coated tablets.

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each film coated tablet contains:

Azithromycin Dihydrate USP

Eq.to Azithromycin : 500 mg

Excipients : Q.S.

Colour : Erythrosine

**3. PHARMACEUTICAL FORM**

Tablet.

For oral administration.

**4. CLINICAL PARTICULARS**

**4.1 Therapeutic indications**

AFITHRO-500 is indicated for the treatment of patients with mild to moderate infections caused by susceptible strains of the designated microorganisms in the specific condition listed below. As recommended dosages, durations of therapy and applicable patient population vary among these infections.

**4.2 Posology and method of administration**

- For oral dosage forms tablets:
- For treatment of infections:
- Adults—500 to 2000 milligrams (mg) once a day as a single dose. Depending on the type of infection, this may be followed with doses of 250 to 500 mg once a day for several days.
- Children and infants 6 months of age and older—Dose is based on body weight and must be determined by your doctor. However, the recommended dose is 10 to 30 milligrams (mg) per kilogram (kg) once a day as a single dose. Depending on the type of infection, this may be followed with doses of 5 to 12 mg/kg once a day for several days.
- Infants below 6 months of age—Use and dose must be determined by your doctor.

## MODULE: 1 ADMINISTRATIVE PARTICULARS OF THE PRODUCT

### 1.3 PRODUCT INFORMATION

#### 1.3.1 SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)

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#### 4.3 Contraindications

Contraindicated in patients with known hypersensitivity to azithromycin, erythromycin, any macrolide or ketolide antibiotic.

#### 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, and 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, Methylethylergonovine, 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 B:** 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 foetus.

**Lactation:** Studies in women suggest that this medication possess minimal risk to the infant when used during breastfeeding.

#### 4.7 Undesirable effects

- Diarrhoea;
- Difficulty breathing or swallowing;
- Hives;
- Hoarseness;

## MODULE: 1 ADMINISTRATIVE PARTICULARS OF THE PRODUCT

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#### 1.3.1 SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)

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- 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;

#### 4.8 Overdose

People who take too much Azithromycin may have overdose symptoms that could include, but are not limited to:

- Nausea
- Diarrhoea
- Vomiting
- Loss of strength.

If you happen to overdose, seek medical attention immediately.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

**Pharmacotherapeutical Category:** anti-bacterials for systemic use; macrolids; azithromycin  
**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

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.

## 6. PHARMACEUTICAL PARTICULARS

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## MODULE: 1 ADMINISTRATIVE PARTICULARS OF THE PRODUCT

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##### 6.1 List of excipients

| Name of Material           | Specification |
|----------------------------|---------------|
| Maize Starch               | BP            |
| Lactose                    | BP            |
| Colloidal Anhydrous Silica | BP            |
| Povidone                   | IHS           |
| Purified water             | BP            |
| Magnesium stearate         | BP            |
| Purified Talc              | BP            |
| Croscarmellose sodium      | BP            |
| Film coat erythrosine      | IHS           |
| Methylene chloride         | BP            |
| Isopropyl alcohol          | BP            |

##### 6.2 Incompatibilities

NA

##### 6.3 Shelf life

36 Months

##### 6.4 Special precaution for storage

Store below 30°C. Protected from light.

KEEP OUT OF REACH OF CHILDREN

##### 6.4 Special Nature and contents of container

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

## 7. MARKETING AUTHORISATION HOLDER



Ahmedabad

Gujarat, India.

E-mail: [info@sagalabs.com](mailto:info@sagalabs.com)

URL: [www.sagalabs.com](http://www.sagalabs.com)

## 8. MARKETING AUTHORISATION NUMBER(S)

G/25/1877

# AFITHRO-500

## Azithromycin 500 mg Tablets

Each film coated tablet contains:

Azithromycin Dihydrate USP

Equivalent to Azithromycin : 500 mg

Excipients : QS

Color: Erythrosine

### Dosage:

As directed by the physician.

### Storage:

Store below 30°C in a cool & dry place.

Protect from heat, light & moisture.

Keep out of reach of children.

NAFDAC Reg. No.:

Mfg. Lic. No.: G/28/1330

Artwork No.: 52498F01-00

Manufactured in India by:



Survey No. 198/2 & 198/3, Chachrawadi Vasna,  
Tal.: Sanand, Dist.: Ahmedabad 382 210, INDIA.

Manufactured for:

**Topbrands** +

pharmaceuticals Ltd

No. 3, Osuntokun Avenue, Old Bodija Estate,  
Bodija, Ibadan, Oyo State, Nigeria.

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pharmaceuticals ltd

# AFITHRO-500

## Azithromycin 500 mg Tablets

1 x 3 Tablets

**AFITHRO-500**  
Azithromycin 500 mg Tablets

Artwork No.: 52/98801-00

Each film coated tablet contains:  
Azithromycin Dihydrate USP  
Equivalent to Azithromycin : 500 mg  
Excipients : QS  
Color: Erythrosine

**Dosage:** As directed by the physician.

**Storage:** Store below 30°C in a cool & dry place.  
Protect from heat, light & moisture.

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8 99 0 2 2 9 7 8 0 2 4 9 8 1

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1 x 3 Tablets

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Azithromycin 500 mg Tablets

Manufactured in India by:

 **SAGA**  
LIFESCIENCES LIMITED

Survey No. 1882 & 1962, Chachowadi, Vasna,  
Dist. Sakinaka, Dist. Ahmednagar 410 210, INDIA.

Mfg. Lic. No.: G/28/1330

Manufactured for:

 **Topbrands** +  
pharmaceuticals ltd

No. 3, Osuntokun Avenue, Old Bodija Estate,  
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NAFDAC Reg. No.:

Batch No.:

Mfg. Date:

Exp. Date:

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#### 4.6 Pregnancy and lactation

**Pregnancy B:** Studies have failed to demonstrate a risk to the fetus and there are no adequate & well-controlled studies in pregnant women, but adequate studies in pregnant women have failed to demonstrate a risk to the fetus.

**Lactation:** Studies in women suggest that this medication possess minimal risk to the infant when used during breastfeeding.

#### 4.7 Undesirable effects

- Diarrhoea;
- Difficulty breathing or swallowing;
- Hives;
- Hoarseness;
- Itching;
- Mild skin rash;
- Rapid, pounding, or irregular heartbeat;
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- Stomach pain;
- Swelling of the face, throat, tongue, lips, eyes, hands, feet, ankles, or lower legs;
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Keep out of reach of children.

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