

Azithromycin

COMPOSITION

AZIGO-500 Tablets

Each tablet contains:

Azithromycin Dihydrate equivalent to

Azithromycin (anhydrous) USP 500 mg

AZIGO -250 Tablets

Each tablet contains:

Azithromycin Dihydrate equivalent to

Azithromycin (anhydrous) USP 250 mg

AZIGO-200 Rediuse Oral Suspension

Each 5 ml contains:

Azithromycin USP (as dihydrate) equivalent to

Azithromycin (anhydrous) 200 mg

Flavoured syrup base q.s.

AZIGO -100 Rediuse Oral Suspension

Each 5 ml contains:

Azithromycin USP (as dihydrate) equivalent to

Azithromycin (anhydrous) 100 mg

Flavoured syrup base q.s.

AZIGO-100 DT

Each dispersible tablet contains:

Azithromycin Dihydrate equivalent to

Azithromycin (anhydrous) USP 100 mg

INDICATIONS

Adults**Oral Tablets**

Azithromycin tablets are indicated in the treatment of the following infections:

- **Acute bacterial exacerbations of chronic obstructive pulmonary disease** due to *Haemophilus influenzae*, *Moraxella catarrhalis* or *Streptococcus pneumoniae* .
- **Acute bacterial sinusitis** due to *Haemophilus influenzae* , *Moraxella catarrhalis* or *Streptococcus pneumoniae* .
- **Community-acquired pneumonia** due to *Chlamydia pneumoniae* , *Haemophilus influenzae* , *Mycoplasma pneumoniae* or *Streptococcus pneumoniae* in patients appropriate for oral therapy.
- **Pharyngitis/tonsillitis** caused by *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 *Streptococcus agalactiae* . Abscesses usually require surgical drainage.
- **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 clinical trials, the efficacy of azithromycin in the treatment of chancroid in women has not been established.

AZIGO , at the recommended dose, should not be relied upon to treat syphilis.**Paediatric Use****Rediuse suspension and DT**Upper respiratory tract infections (URTIs)

- **Acute otitis media** caused by *Haemophilus influenzae*, *Moraxella catarrhalis* or *Streptococcus pneumoniae*.
- **Pharyngitis/tonsillitis** caused by *Streptococcus pyogenes* as an alternative to first-line therapy in individuals who cannot use first-line therapy.
- **Sinusitis** caused by *Haemophilus influenzae*, *Moraxella catarrhalis* or *Streptococcus pneumoniae* .

Lower respiratory tract infections (LRTIs)

- **Community-acquired pneumonia** due to *Chlamydia pneumoniae*, *Haemophilus influenzae*, *Mycoplasma pneumoniae* or *Streptococcus pneumoniae* in patients appropriate for oral therapy.
- **Acute bronchitis** caused by *Chlamydia pneumoniae*, *Haemophilus influenzae*, *Mycoplasma pneumoniae* or *Streptococcus pneumoniae*.

Uncomplicated skin and soft tissue infections (SSTIs)

- **Furunculosis, pyoderma and impetigo** due to *Staphylococcus aureus*, *Streptococcus pyogenes* and *Streptococcus agalactiae*.

Uncomplicated genital infections (in adolescents and older children)

- **Urethritis** and **cervicitis** due to *Chlamydia trachomatis*.

DOSAGE AND ADMINISTRATION

Adults

Oral Tablets

Dosage

Infection*	Recommended Dose/Duration of Therapy
Community-acquired pneumonia (mild severity) Pharyngitis/tonsillitis (second-line therapy) Skin/skin structure (uncomplicated)	500 mg as a single dose on day 1, followed by 250 mg once daily on day 2 through day 5
Acute bacterial exacerbations of chronic obstructive pulmonary disease (mild to moderate)	500 mg o.d. × 3 days OR 500 mg as a single dose on day 1, followed by 250 mg once daily on day 2 through day 5
Acute bacterial sinusitis	500 mg o.d. × 3 days

*Due to the indicated organisms

AZIGO tablets can be taken with or without food.

Paediatric Use

Rediuse Oral suspension and DT

Age	Indications	1-day Regimen	3-days Regimen	5-days Regimen
From 6 months and above	Acute otitis media	30 mg/kg single dose	10 mg/kg once daily	Day 1: 10 mg/kg single dose Days 2-5: 5 mg/kg/day
	Acute bacterial sinusitis		10 mg/kg once daily	
	Community-acquired pneumonia/Acute bronchitis		10 mg/kg once daily	Day 1: 10 mg/kg single dose Days 2-5: 5 mg/kg/day
	Uncomplicated SSTIs		10 mg/kg once daily	Day 1: 10 mg/kg single dose Days 2-5: 5 mg/kg/day
From 2 years and above	Pharyngitis/Tonsillitis		12 mg/kg once daily	

Effectiveness of the 1-day regimen in paediatric patients with community-acquired pneumonia has not been established. Effectiveness of the 5-day or 1-day regimen in paediatric patients with acute bacterial sinusitis has not been established. The safety of re-dosing azithromycin in paediatric patients who vomit after receiving 30 mg/kg as a single dose has not been established. In clinical studies involving 487 patients with acute otitis media given a single 30 mg/kg dose of azithromycin, 8

patients who vomited within 30 minutes of dosing were re-dosed at the same total dose.

AZIGO (for rediuse oral suspension/DT) can be taken with or without food.

CONTRAINDICATIONS

Azithromycin is contraindicated in patients with a known hypersensitivity to azithromycin, erythromycin, and any macrolide or ketolide antibiotic.

PACKAGING INFORMATION

- Azigo -500 Tablets** Blister pack of 3 tablets
- Azigo -250 Tablets**Blister pack of 6 tablets
- Azigo -200 Rediuse Oral Suspension**15 ml bottle
- Azigo -100 Rediuse Oral Suspension**15 ml bottle
- Azigo -100 DT** Alu-Alu Pack of 10

