

New Registration



QUALITATIVE AND QUANTITATIVE COMPOSITION

Film coated tablets

Each film coated tablet contains azithromycin dihydrate 524 mg equivalent to azithromycin 500 mg

Powder for oral suspension

Each 5ml after reconstitution contains azithromycin dihydrate 200 mg equivalent to azithromycin 200mg

PHARMACEUTICAL FORM

Film coated tablets

Powder for oral suspension

Physical characters

Film coated tablets

Yellow oblong biconvex film coated tablet bisected from one side. Xithrone 500 mg film coated tablet can be divided into equal doses.

Powder for oral suspension

Before reconstitution: White to off white granular powder having faintest odor

After reconstitution: Very transparent pale yellow suspension

Clinical Particulars

Therapeutic indications

Adults

Azithromycin is indicated for use in adults for the treatment of the following infections of mild to moderate severity:

Lower respiratory tract infections

Acute bacterial bronchitis

Due to Streptococcus pneumoniae, Haemophilus influenzae or Moraxella catarrhalis

Community acquired pneumonia

Due to Streptococcus pneumoniae or Haemophilus influenzae in patients suitable for outpatient oral treatment

Community acquired pneumonia caused by susceptible organisms in patients who require initial intravenous therapy

Disseminated infection due to Mycobacterium avium-intracellulare complex (MAC) disease

Upper respiratory tract infections

Acute sinusitis

Due to Streptococcus pneumoniae or Haemophilus influenzae

Acute streptococcal pharyngitis

Note: Penicillin is the usual drug of choice in the treatment of Streptococcus pyogenes pharyngitis, including the prophylaxis of rheumatic fever. Azithromycin appears to be almost as effective in the treatment of Streptococcus pharyngitis. However, substantial data establishing the efficacy of azithromycin in the subsequent prevention of rheumatic fever are not available at present.

Acute otitis media

Uncomplicated skin and skin structure infections

Uncomplicated infections due to Staphylococcus aureus, Streptococcus pyogenes or Streptococcus agalactiae. Abscesses usually require surgical drainage.

Sexually transmitted diseases

Uncomplicated urethritis and cervicitis due to Chlamydia trachomatis or non multi-resistant Neisseria gonorrhoeae.

Note: At the recommended dose azithromycin cannot be relied upon to treat syphilis. As with other drugs for the treatment of non-gonococcal infections, azithromycin may mask or delay the symptoms of existing syphilis and therefore concurrent infection with Treponema pallidum should be excluded. Appropriate tests should be performed for the detection of syphilis and treatment should be initiated as required.

Pilo-inflammatory disease

Caused by susceptible organisms: Chlamydia trachomatis, Neisseria gonorrhoeae, Mycoplasma hominis, in patients who require initial intravenous therapy.

Chlamydia trachomatis conjunctivitis and trachoma

Prevention of infection due to Mycobacterium avium-intracellulare complex (MAC) disease

When used as the sole agent or in combination with rifabutin at its approved dose, in adults with HIV infection and CD4 cell count less than or equal to 75 cells/mm³.

Disseminated infection due to Mycobacterium avium-intracellulare complex should be excluded by a negative blood culture prior to commencement of therapy.

Paediatric population

Azithromycin is indicated for use in children for the treatment of the following infections:

Lower respiratory tract infections

See ADULT INDICATIONS above

Upper respiratory tract infections

See ADULT INDICATIONS above

Uncomplicated skin and skin structure infections

See ADULT INDICATIONS above

Prevention of infection due to Mycobacterium avium-intracellulare complex (MAC) disease

When used as the sole agent or in combination with rifabutin at its approved dose, in children aged more than 12 years with HIV infection and CD4 cell count less than or equal to 75 cells/mm³. Chemotherapy infection due to Mycobacterium avium-intracellulare complex should be excluded by a negative blood culture prior to commencement of therapy.

Acute Streptococcal pharyngitis/tonsillitis

Note: Penicillin is the usual drug of choice in the treatment of Streptococcus pyogenes pharyngitis, including the prophylaxis of rheumatic fever. The 20 mg/kg azithromycin dose appears to be as effective as penicillin in the treatment of Streptococcal pharyngitis. However, substantial data establishing the efficacy of azithromycin in the subsequent prevention of rheumatic fever are not available at present.

Chlamydia trachomatis conjunctivitis and trachoma

In children 12 months of older

Dose and method of administration

Adults

Azithromycin should be given as a single daily dose

Tablets and PDS may be taken with food

Administration of capsules with or following a meal significantly reduces the bioavailability. Therefore, capsules must be taken at least 1 hour before or 2 hours after a meal.

Adults

Sexually transmitted uncomplicated urethritis and cervicitis due to Chlamydia trachomatis or susceptible Neisseria gonorrhoeae

1 g in a single dose

Conjunctivitis and trachoma due to Chlamydia trachomatis

1 g either as a single dose or once weekly for up to 3 weeks

Following IV therapy for the treatment of COT

500 mg as a single daily dose to complete 7 to 10 days course of therapy

Following IV therapy for the treatment of pillo-inflammatory disease

250 mg as a single daily dose to complete 7 day course of therapy

Prevention of disseminated MAC disease in adults with HIV infection

1200 mg taken as a single dose once weekly, either alone, or in combination with rifabutin, at its recommended dosage

All other indications including urethritis related to oral treatment of CAP: 500 mg taken as 1 g once weekly or 1 g alternate

Total dose of 15 tablets (as 500 mg on Day 1, then 20 mg daily for days 2 to 5 or alternatively as 500 mg daily for 5 days)

Children

Conjunctivitis and trachoma due to Chlamydia trachomatis in children 12 months of older

20 mg/kg either as a single dose or once weekly for up to 3 weeks

Prevention of disseminated MAC disease in children aged more than 12 years with HIV infection

1200 mg taken as a single dose once weekly, either alone, or in combination with rifabutin, at its recommended dosage

All other indications including urethritis related to oral treatment of CAP: 500 mg taken as 1 g once weekly or 1 g alternate

Total dose of 15 tablets (as 500 mg on Day 1, then 20 mg daily for days 2 to 5 or alternatively as 500 mg daily for 5 days)

Adults

Conjunctivitis and trachoma due to Chlamydia trachomatis in children 12 months of older

20 mg/kg either as a single dose or once weekly for up to 3 weeks

Prevention of disseminated MAC disease in children aged more than 12 years with HIV infection

1200 mg taken as a single dose once weekly, either alone, or in combination with rifabutin, at its recommended dosage

All other indications

10 mg/kg as a single dose on the first day followed by 5 mg/kg/day on days 2 to 5 for children weighing <45 kg taken as per adults.

Method of administration

Oral suspension is better to be taken with food.

Contraindications

Azithromycin is contraindicated in:

Patients with hypersensitivity to azithromycin, erythromycin, any other macrolide or ketolide antibiotic, or to any of the excipients.

Warnings - contraindicated in patients with a history of cholestatic jaundice or liver dysfunction.

Special warnings and precautions for use

Use with caution in the following circumstances:

In the treatment of pneumonia, azithromycin has been shown to be safe and effective only in the treatment of community-acquired pneumonia (CAP) of mild severity due to Streptococcus pneumoniae or Haemophilus influenzae in patients appropriate for outpatient oral therapy. Azithromycin should be used in patients with pneumonia who are judged to be appropriate for outpatient oral therapy because of moderate to severe disease or risk factors such as any of the following:

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immunosuppression

- patients with co-trimoxazole

- patients with immun

