

180mm

MACROMAX

(Azithromycin Tablets)



350mm

Description

MACROMAX is the trademark of Azithromycin, a systemic antibiotic.
Each MACROMAX 250 Film Coated Tablet contains 250 mg of Azithromycin.
Each MACROMAX 500 Film Coated Tablet contains 500 mg of Azithromycin.

Excipients for tablets: pregelatinized starch, anhydrous calcium hydrogen phosphate, croscarmellose sodium, sodium lauryl sulphate, magnesium stearate, hydroxypropylmethyl cellulose, polyethylene glycol and titanium dioxide.

CHEMISTRY

Azithromycin is: (2R,3S,4R,5R,8R,10R,11R,12S,13S,14R)-13-[(2,6-Dideoxy-3-C-methyl-9-O-methyl-L-ribo-hexopyranosyl)oxy]-2-ethyl-3,4,10-trihydroxy-3,5,6,8,10,12,14-heptamethyl-11-[[3,4,6-trihydroxy-3-(dimethylamino)-ID-xylotrihexopyranosyl]oxy]-1-oxa-6-azacyclotetradecan-15-one.

CLINICAL PHARMACOLOGY

Azithromycin acts by binding to the 50S ribosomal subunit of susceptible microorganisms and, thus, interfering with microbial protein synthesis. The antimicrobial spectrum for the activity of Azithromycin covers the following organisms:

Gram-positive aerobic bacteria: Staphylococcus aureus, Streptococcus pyogenes (group A beta-haemolytic streptococci), Streptococcus pneumoniae, alpha-haemolytic streptococci (viridans group) and other streptococci and Corynebacterium diptheriae. Azithromycin demonstrates cross-resistance with erythromycin-resistant gram-positive strains including Streptococcus faecalis (enterococci) and most strains of methicillin-resistant staphylococci.

Gram-negative aerobic bacteria: Haemophilus influenzae and parainfluenzae, Moraxella catarrhalis, Acinetobacter species, Yersinia species, Legionella pneumophila, Bordetella pertussis and parapertussis and Plesiomonas shigella species, Pasteurella species, Vibrea cholerae and parahaemolyticus.

Anaerobic bacteria: Bacteroides fragilis and Bacteroides species, Clostridium perfringens, Peptococcus and Peptostreptococcus species, Fusobacterium necrophorum and Propionibacterium acnes.

Micro-organisms causing sexually transmitted diseases: Chlamydia trachomatis, Treponema pallidum, Neisseria gonorrhoea and Haemophilus ducreyi. Other micro-organisms: Borrelia burgdorferi (Lyme disease), Chlamydia pneumoniae (TWAR), Mycoplasma pneumoniae and hominis, Ureaplasma urealyticum, Mycobacterium avium, Campylobacter species and Listeria monocytogenes.

INDICATIONS

- Infections of the upper respiratory tract including sinusitis, pharyngitis and tonsillitis.
- Infections of the lower respiratory tract including bronchitis and pneumonia.
- Otitis media.
- Infections of skin and soft tissues.
- Uncomplicated genital infections caused by Chlamydia trachomatis or Neisseria gonorrhoea (non multi-resistant strains). Concurrent use in Treponema pallidum should be excluded.

DOSAGE

Usual adult dose and children with body weight over 45 kg:
3-day therapy: 500 mg of Azithromycin daily (500 mg once daily for 3 days) or alternative 5-day therapy: 500 mg once daily in first day, followed by 250 mg once daily in the lasting 4 days.

Sexually transmitted diseases: 1 g of Azithromycin once.

Notes:

- Azithromycin is not the drug of first choice for the treatment of tonsillitis or pharyngitis due to streptococci or for the prophylaxis of rheumatic fever. So far, there are no epidemiologic long-term studies of the efficacy of such a prophylaxis or of the frequency of possible late sequelae after 5-day therapy.
- The efficacy of a 5-day regimen of Azithromycin in the treatment of patients with pneumonia is sufficient in most cases.
- No dosage adjustment is required in patients with impaired renal function up to a creatinine clearance of ≥ 40 ml/min, however, caution should be exercised when using MACROMAX in patients with severe renal insufficiency (creatinine clearance < 40 ml/min).
- MACROMAX should be administered at least 1 hour before or at the earliest, 2 hours after food.

ADVERSE EFFECTS

- Gastrointestinal tract: Disorders in the form of diarrhea and loose stools, abdominal complaints (pain or spasms), nausea, vomiting and flatulence may occasionally occur. In patients with severe and persistent diarrhoea, treatment with Azithromycin should be immediately terminated.
- Hypersensitivity reactions: Rare during Azithromycin treatment.

USE IN PREGNANCY AND LACTATION

Azithromycin may be administered to pregnant and nursing women only if life-threatening conditions or when alternative treatment is not possible, as a final assessment of the safety of this therapy is not possible yet. FDA Pregnancy Category B.

INTERFERENCE WITH CLINICAL AND LABORATORY TESTS

A reversible increase in liver enzymes (transaminases, alkaline phosphatase) and in serum bilirubin were rarely observed.

DRUG INTERACTIONS

- Mineral antacids should not be taken simultaneously with Azithromycin as a study revealed peak serum levels reduced by up to 30%.
- Although no experience is available so far, vasoconstricting effects with circulatory disorders, in particular of fingers and toes, cannot be excluded if Azithromycin and dihydroergotamine or non-hydrated ergot alkaloids are administered concomitantly.

Therefore concomitant administration should be avoided for safety reasons.

- Since interactions between theophylline and some macrolides have been described, patients should be monitored regarding typical reactions of increased theophylline levels when Azithromycin and theophylline are co-administered.

- Macrolide antibiotics are known to interact with triazolam, cyclosporin and digoxin. For Azithromycin, sufficient data are not available but the possibility of interactions should be borne in mind.

- The potential of parallel resistance between Azithromycin and macrolide antibiotics (e.g. erythromycin) as well as lincosamin and clindamycin should be borne in mind. Therefore, co-administration of several drugs of this class is not recommended.

CONTRAINDICATIONS

- Azithromycin is contraindicated in patients with known hypersensitivity to Azithromycin or macrolide antibiotics such as erythromycin.
- Azithromycin should not be used in patients with severe hepatic diseases, as it is mainly excreted via the liver.

WARNINGS

Because of an existing cross-resistance to erythromycin-resistant gram-positive strains and most strains of methicillin-resistant staphylococci, Azithromycin should not be used in these cases.

PRECAUTIONS

As with any antibiotic preparation, observation for signs of superinfection with nonsusceptible organisms, including fungi, is recommended and appropriate therapy should be instituted, if necessary.

HOW SUPPLIED

Boxes of 6 blistered Tablets of MACROMAX 250.

Boxes of 3 blistered Tablets of MACROMAX 500.

Hospital packs of different presentations.

Keep this out of reach of children. Store below 30°C. Protect from light & moisture

Do not use after the expiry date shown on the package.

This is a Medicament

- Medicament is a product which affects your health and its consumption contrary to instruction is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instruction of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of the reach of children.

Council of Arab Health Ministers

Union of Arab Pharmacists

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