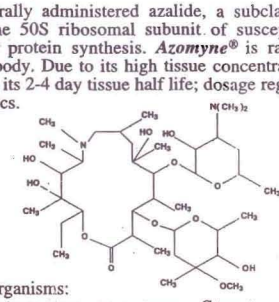
Azomyne®

Azithromycin

Properties:

Azomyne® (azithromycin) is an acid stable orally administered azalide, a subclass of macrolide antibiotics. It acts by binding to the 50S ribosomal subunit of susceptible organisms and thus interfering with microbial protein synthesis. ***Azomyne®*** is rapidly absorbed and widely distributed throughout the body. Due to its high tissue concentrations which exceed those in plasma up to 50 times, and its 2-4 day tissue half life; dosage regimen of azithromycin differs from that of other antibiotics.



Antimicrobial activity:

Azomyne® is active against the following micro-organisms:

Gram-positive aerobic bacteria: Streptococcus pyogenes, Streptococcus pneumoniae, Streptococcus viridans, other streptococcus species, Staphylococcus aureas and Corynebacterium diphtheriae.

Gram-negative aerobic bacteria: Moraxella catarrhalis, Haemophilus influenzae and parainfluenzae, Acinetobacter species, Yersinia species, Legionella pneumophila, Bordetella pertussis and parapertussis, Plesimonas shigella species, Pasteurella species, Vibrio cholerae and Parahemolyticus. Activity against Escherichia coli, Salmonella enteritidis and typhi, Enterobacter species, Aeromonas hydrophila, and Klebsiella species is variable, therefore, susceptibility testing should be considered.

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

Micro-organisms causing sexually transmitted diseases: Chlamydia trachomatis, Treponema pallidum, Neisseria gonorrhoeae,and Haemophilus ducreyi.

Other micro-organisms: Chlamydia pneumoniae, Borrelia burgdorferi,Toxoplasma gondii, Mycoplasma pneumoniae and hominis , Ureaplasma urealyticum, Pneumocystis carinii, Mycobacterium avium,Campylobacter species, and Listeria monocytogenes.

Indications:

Azomyne® is indicated for the treatment of:

- Upper respiratory tract infections (including sinusitis, tonsillitis and pharyngitis).
- Lower respiratory tract infections (including bronchitis and pneumonia).
- Otitis media.
- Skin and soft tissue infections.
- Sexually transmitted diseases caused by Chlamydia trachomatis or susceptible Neisseria gonorrhoeae.

Dosage & Administration:

Azomyne® is given as a once daily dose at least 1 hour before or 2 hours after food.

Adults and children weighing 45 kg or more:

- Sexually transmitted diseases: 1 g azithromycin given as a single dose.
- All other indications: the total dose is 1.5 g of azithromycin given as: 3-day or 5-day regimen:
  - 3-day regimen: 500 mg of azithromycin given as a single dose for three days.
  - Alternative 5-day regimen: 500 mg of azithromycin as a single dose on day 1 followed by 250 mg azithromycin on days 2-5.

Children weighing less than 45 kg: 10 mg/kg as a single dose for 3 consecutive days.

- In most cases of pneumonia, the 5-day regimen of azithromycin is sufficient.

Drug interactions:

- Mineral antacids: azithromycin and mineral antacids should not be taken simultaneously; since mineral antacids reduce the peak plasma level of azithromycin (without affecting the extent of absorption).
- Cimetidine: has no effect on azithromycin absorption; therefore, it can be co-administered with azithromycin.
- Theophylline: clinical studies have not revealed any evidence of interaction between azithromycin and theophylline: since interaction between theophylline and some macrolides has been reported, careful monitoring of patients taking theophylline and azithromycin concomitantly is advised.
- Some macrolides are known to interact with digoxin, cyclosporin, and triazolam, until further data are available for azithromycin, the possibility of azithromycin interaction with these drugs should be born in mind.
- In healthy subjects studies, co-administration of azithromycin does not significantly affect carbamazepine and methylpredinsolone level.
- For the potential of cross-resistance, it is not recommended to adminster azithromycin with other macrolides (such as erythromycin) as well as lincomycin and clindamycin.

Contraindications:
Azithromycin is contraindicated in patients with a known hypersensitivity to it or any of the macrolide antibiotics.

Adverse reactions:
Gastrointestinal adverse reactions such as diarrhea, abdominal pain, vomiting, and nausea may occasionally occur. Reversible increase in liver enzymes (transaminase and alkaline phosphatase) and in serum bilirubin was rarely observed.

Precautions:
- Due to the theoretical possibility of ergotism, avoid concomitant use of azithromycin and ergot alkaloids.
- Azithromycin should be used with caution in patients with impaired hepatic function or liver diseses.
- No dose reduction is required in mild renal impairment (creatinine clearance ≥ 40 ml/min), but caution should be exercised in patients with more severe renal insufficiency.
- **Pregnancy:** category B, there are no adequate and well controlled studies in pregnant women; use during pregnancy only if clearly needed.
- **Lactation:** it is not known whether azithromycin is excreted in breast milk. Because many drugs are excreted in human milk, caution should be exercised when azithromycin is administered to a nursing woman.

Warnings:
- Like other drugs, allergic reactions including anaphylaxis and angioedema have been reported rarely in patient on azithromycin therapy. If allergic reactions occur, the drug should be discontinued and appropriate therapy should be instituted.
- In preclinical studies, azithromycin in high dose has been noted to cause reversible phospholipidosis. there is no evidence that this is of relevance to the normal use of azithromycin in humans.
- Treatment with broad-spectrum antibacterial agents may lead to overgrowth of non-susceptible organisms and antibiotic associated colitis may occur.

Overdosage:
Data on overdosage are not available. Should overdosage occur, gastric lavage and general supportive measures are indicated.

Information for the patient:
- Take ***Azomyne®*** at least 1 hour before meals or 2 hours after.
- Do not take ***Azomyne®*** with antacids containing Aluminum or Magnesium.
- Swallow the whole capsule with some liquid.
- Discard unused suspension after 5 days of reconstitution.

Presentation:

Azomyne® **Capsules**	:	Each capsule contains 250 mg Azithromycin (dihydrate) USP in packs of 6's.
Azomyne® **Dry Suspension:**		Each 5 ml contains 200 mg Azithromycin (dihydrate) USP in bottles of 15 ml after reconstitution.
Azomyne® **Dry Suspension:**		Each 7.5 ml contains 300 mg Azithromycin (dihydrate) USP in bottles of 22.5 ml after reconstitution.

(This is a Medicament - Keep medicaments out of the reach of children)

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription , method of use and the instructions of the phamacist 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.

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