Azikil

Azithromycin

Composition

Azikil 500 Tablet: Each film coated tablet contains Azithromycin Dihydrate USP equivalent to Azithromycin 500 mg.
Azikil 20 ml Powder for Suspension: After reconstitution, each 5 ml suspension contains Azithromycin Dihydrate USP equivalent to Azithromycin 200 mg.
Azikil 35 ml Powder for Suspension: After reconstitution, each 5 ml suspension contains Azithromycin Dihydrate USP equivalent to Azithromycin 200 mg.
Azikil 50 ml Powder for Suspension: After reconstitution, each 5 ml suspension contains Azithromycin Dihydrate USP equivalent to Azithromycin 200 mg.

Pharmacology

Azithromycin is an azalide antibiotic, a subclass of macrolide antibiotic. It acts by binding to the 50s ribosomal subunit of susceptible microorganisms and thus interfering with microbial protein synthesis. Azithromycin has been shown to be active against most strains in the following microorganisms, both In vitro and in clinical infections:
Gram-positive microorganisms: *Staphylococcus aureus, Streptococcus agalactiae, Streptococcus pneumoniae, Streptococcus pyogenes.*
Gram-negative microorganisms: *Haemophilus ducreyi, Haemophilus influenzae, Moraxella catarrhalis, Neisseria gonorrhoeae, Escherichia coli.*

Indication

Azithromycin is indicated for infections caused by susceptible organisms in-

- Upper respiratory tract infections including sinusitis, pharyngitis and tonsillitis
- Lower respiratory tract infections including bronchitis, acute bacterial exacerbations of chronic obstructive pulmonary disease (COPD)
- Otitis media
- Skin and soft tissue infections including cellulitis, pyoderma, erysipelas, wound infections
- Diarrhea, Shigellosis
- Sexually transmitted diseases, especially in the treatment of non-gonococcal urethritis and cervicitis due to *Chlamydia trachomatis*
- Genital ulcer disease in men due to *Haemophilus ducreyi* (chancroid)
- Mild or moderate typhoid due to multiple-antibacterial resistant organisms
- Prophylaxis against a-hemolytic (viridans group) streptococcal bacterial endocarditis
- Other infections including odontogenic infections, bartonella infections, toxoplasmosis, babesiosis

Dose and Administration

a) Route of administration: Oral
Azithromycin Tablet & Powder for Suspension can be taken with or without food.
• *Adult*: For respiratory tract infections, otitis media and skin & soft tissue infections: 500 mg once daily for 3 days or an alternative to this as 500 mg once on day 1, followed by 250 mg once daily for next 4 days.
• For sexually transmitted diseases like genital ulcer, non-gonococcal urethritis and cervicitis due to *Chlamydia trachomatis* : a single 1 gm (1000 mg) dose.
• For the treatment of urethritis and cervicitis due to *Neisseria gonorrhoeae* : a single 2 gm (2000 mg) dose. In typhoid, 500 mg once daily for 7 days.
• In Cholera, a single 1 gm (1000 mg) dose.
• In Shigellosis, 500 mg once on day 1, followed by 250 mg once daily for next 4 days.

• *Children:*

Age/body weight	Daily dose	Measuring cup/spoon	Duration
From 1 month	10 mg/kg	According to Physician's recommendation	3 days
15-25 kg	200 mg	5 ml (1 tea spoonful)	3 days
26-35 kg	300 mg	7.5 ml ($1^1/_2$ tea spoonful)	3 days
36-45 kg	400 mg	10 ml (2 tea spoonful)	3 days

• *Elderly*: same as for adults.

Contra-indications

Azithromycin is contraindicated in patients hypersensitive to Azithromycin or any other macrolide antibiotic. Co-administration of ergot derivative and Azithromycin is contraindicated. Azithromycin is contraindicated in patients with hepatic diseases.

Warning & Precautions

As with any antibiotic, observation for signs of super infection with non-susceptable organisms, including fungi, is recommended. Precaution should be taken in patients with more severe renal impairment.

Side effects

a) Common: Azithromycin is well tolerated with a low incidence of side effects. The side effects include nausea, vomiting, abdominal discomfort (pain/cramps), flatulence, diarrhea, headache, dizziness, and skin rashes and are reversible upon discontinuation of therapy.
b) Rare: Reversible elevations in liver transaminases have been observed occasionally. Transient mild reductions in neutrophil counts have occasionally been observed in clinical trials, although causal relationship to Azithromycin has not been established.

Use in Pregnancy & Lactation

Pregnancy: US FDA pregnancy category B. In the animal studies, no evidence of harm to the fetus due to Azithromycin was found.
Lactation: It is not known whether Azithromycin is excreted in human milk. Caution should be exercised when administered to nursing mother.

Use in Children & Adolescents

Should be used as per direction of physician.

Drug interactions

a) With medicine: Peak serum levels but not the total extent of absorption were reduced by the presence of magnesium and aluminum-containing antacids. Azithromycin should be taken at least 1 hr before or 2 hrs after these antacids. In patients receiving ergot alkaloids, Azithromycin should be avoided concurrently because of the possibilty of ergotism result in from interaction of Azithromycin with the cytochrome P-450 system However, no cases of such interaction have been reported. Macrolides have been known to increase the plasma concentration of digoxin and cyclosporine. Therefore, if co-administration is necessary caution should be exercised and serum levels of digoxin and cyclosporine should be checked.
b) With food & others: No adequate data are available.

Direction for reconstitution of suspension

Shake the bottle to loosen powder.
• **20 ml:** Add 15 ml (3 tea spoonful) with the help of supplied measuring cup of boiled and cooled water to the dry powder of the bottle.
• **35 ml:** Add 25 ml (5 tea spoonful) with the help of supplied measuring cup of boiled and cooled water to the dry powder of the bottle.
• **50 ml:** Add 35 ml (7 tea spoonful) with the help of supplied measuring cup of boiled and cooled water to the dry powder of the bottle.
For ease of preparation, add boiled and cooled water in two proportions. Shake well after each addition until all the powder is in suspension.
• *Note:* Shake the suspension well before each use. Keep the bottle tightly closed. The reconstituted suspension should be stored in a cool and dry place, preferably in refrigerator.

Overdose

There are no data available on overdose with Azithromycin. Typical symptoms of overdosage with macrolide antibiotics include hearing loss, severe nausea, vomiting and diarrhea. Gastric lavage and general supportive measures are indicated.

Storage

Store below 30°C. Protected from light. Keep all medicines out of reach of children.

Packing

Azikil 500 Tablet: Each box contains 12 (3x4) tablets in blister pack.
Azikil 20 ml Powder for Suspension: Each box contains one bottle of Azithromycin powder. After reconstitution as per direction bottle contains 20 ml suspension.
Azikil 35 ml Powder for Suspension: Each box contains one bottle of Azithromycin powder. After reconstitution as per direction bottle contains 35 ml suspension.
Azikil 50 ml Powder for Suspension: Each box contains one bottle of Azithromycin powder. After reconstitution as per direction bottle contains 50 ml suspension.

Manufactured by
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Bogura, Bangladesh

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