

TWEET

[Azithromycin]

Tablets, Capsules & Powder for Oral Suspension

DESCRIPTION:

TWEET (Azithromycin) is nitrogen containing macrolide or azalide for oral administration.

QUALITATIVE AND QUANTITATIVE COMPOSITION:

TWEET (Azithromycin) is available for oral administration as:

1- **TWEET** 500mg Tablets

Each film coated tablet contains:

Azithromycin as Azithromycin dihydrate USP.....500mg

(Product Specs.: USP)

2- **TWEET** 250mg Capsules

Each capsule contains:

Azithromycin as Azithromycin dihydrate USP.....250mg

(Product Specs.: USP)

3- **TWEET** 200mg/5mL Powder for Oral Suspension

Each 5mL contains:

Azithromycin as Azithromycin dihydrate USP.....200mg

(Product Specs.: USP)

CLINICAL PHARMACOLOGY:

Mechanism of Action:

Azithromycin exerts its antibacterial action by binding to the 50S ribosomal subunit of susceptible organisms and thus interfering with microbial protein synthesis and inhibition of peptide translocation.

Microbiology:

Azithromycin has been shown to be active against most isolates of the following micro-organisms.

Aerobic and facultative gram-positive organisms:

Streptococcus pneumoniae, penicillin-resistant, penicillin-intermediate, *Streptococcus pyogenes*,

Staphylococcus aureus, *Streptococcus agalactiae*, *Streptococci* (Groups C, F, G) Viridans group

streptococci, *Corynebacterium diptheriae*. Azithromycin demonstrates cross-resistance with

erythromycin resistant gram-positive strains, including *Streptococcus faecalis* (enterococcus) and most

strains of methicillin-resistant staphylococci.

Aerobic and facultative gram-negative organisms:

Haemophilus ducreyi, *Haemophilus influenzae*, *Moraxella catarrhalis*, *Neisseria Gonorrhoea*, *Bordetella pertussis*,

Legionella pneumophila, *Haemophilus parainfluenzae*, *Acinetobacter* species, *Yersinia* species, *Shigella* species,

Pasteurella species, *Vibrio cholerae* and *parahaemolyticus*, *Plesiomonas shigelloides*.

Anaerobic micro-organisms:

Peptostreptococcus species, *Prevotella bivia*, *Bacteroides fragilis* and *Bacteroides* species, *Clostridium*

perfringens, *Peptococcus* species, *Fusobacterium necrophorum* and *Propionibacterium acnes*.

Others:

Chlamydia pneumoniae, *Chlamydia trachomatis*, *Mycoplasma pneumoniae*, *Ureaplasma urealyticum*,

Escherichia coli, *Salmonella*, *Shigella* spp., *Mycobacterium avium*, *Mycobacterium intracellulare*,

Toxoplasma gondii, *Plasmodium falciparum*.

Pharmacokinetics:

Following oral administration about 40% of the dose of azithromycin is bioavailable. Absorption from the capsule

formulation is reduced by food but there is no significant effect on the bioavailability even after a high fat meal. Peak

plasma concentrations are achieved 2 - 3 hours after a dose but azithromycin is extensively distributed to the tissues

and tissue concentration subsequently remain much higher than those in blood. High concentrations are taken up into

white blood cells. Small amount of azithromycin are demethylated in liver and it is excreted in bile as unchanged drug

and metabolites. About 20% of the amount in the systemic circulation is excreted in the urine. The terminal elimination

half-life is probably in excess of 40 hours.

Special Populations:

Renal insufficiency:

Significant differences in AUC, Cmax and C12r were observed between subjects with severe renal impairment (GFR

<10mL/min) and subjects with normal renal function.

Hepatic insufficiency:

Azithromycin should not be given to patients suffering from severe liver disease.

INDICATIONS:

TWEET (Azithromycin) is indicated for infections caused by susceptible organisms in the conditions listed below:

- Lower & upper respiratory tract infections (including bronchitis, pneumonia, sinusitis, pharyngitis / tonsillitis and

acute otitis media)

- Uncomplicated skin and skin structure infections

- Sexually transmitted diseases (uncomplicated urethritis and cervicitis)

- *Chlamydia trachomatis* conjunctivitis and trachoma in adults and in children 12 months or older.

DOSAGE AND ADMINISTRATION:

TWEET (Azithromycin) tablets and oral suspension can be taken with or without food. The capsule formulation should

be given at least an hour before or 2 hours after meals.

TWEET 250mg Capsules & TWEET 500mg Tablets:

Children and adolescents with a body weight above 45 kg, adults and the elderly:

For all indications except for those given below, the usual adult dose of **TWEET** (Azithromycin) is 500mg as a single dose

daily for 3 days.

Alternatively, an initial dose of 500mg may be followed by 250mg daily for a further 4 days.

In uncomplicated genital infections due to *Chlamydia trachomatis*:

1000 mg as a single oral dose.

For susceptible *Neisseria gonorrhoeae*:

1000mg or 2000mg of azithromycin in combination with 250 mg or 500 mg ceftriaxone according to local clinical

treatment guidelines.

Paediatric population: **TWEET** Capsules are not suitable for children under 45 kg.

TWEET 200mg/5mL Powder for Oral Suspension:

Paediatric population over 45 kg body weight, adults:

The total dosage of azithromycin is 1500 mg which is spread over three days (500 mg once daily).

In uncomplicated genital infections due to *Chlamydia trachomatis*:

1000 mg as a single oral dose.

Children and adolescents (< 18 years):

The total dose in children aged 1 year and older is 30 mg/kg administered as shown below.

Weight (Kg)	3-day therapy	5-day therapy	
	Day 1-3 10mg/kg/day	Day 1 10mg/kg/day	Day 2-5 5mg/kg/day
10 kg	2.5 mL	2.5 mL	1.25 mL
12 kg	3 mL	3 mL	1.5 mL
14 kg	3.5 mL	3.5 mL	1.75 mL
16 kg	4 mL	4 mL	2 mL
17-25 kg	5 mL	5 mL	2.5 mL
26-35 kg	7.5 mL	7.5 mL	3.75 mL
36-45 kg	10 mL	10 mL	5 mL
> 45 kg	12.5 mL	12.5 mL	6.25 mL

Streptococcus pharyngitis: Single dose of 10 mg/kg or 20 mg/kg for 3 days with a maximum daily dose of 500 mg.

Directions for Preparing Oral Suspension:

Fill previously boiled and cooled water upto the mark on the bottle and shake gently. Keep the cap tightly close after

use. The reconstituted suspension can be used for upto 10 days, when store below 30°C.

CONTRAINDICATIONS:

- In patients with known hypersensitivity to azithromycin, erythromycin, any macrolide or ketolide antibiotics.

- In patients with a history of cholestatic jaundice/hepatic dysfunction associated with prior use of azithromycin

- To use concurrently with ergot derivatives.

PRECAUTIONS:

Azithromycin should not be used in patients with pneumonia who are judged to be inappropriate for oral therapy

because of risk factors such as:

- Patients with cystic fibrosis

- Patients with nosocomially acquired infections

- Patients with known or suspected bacteremia

- Patients requiring hospitalisation

- Elderly or debilitated patients

- Immunocompromised patients

- As with any antibiotic preparation, observation for signs of superinfection with non-susceptible organisms

including fungi, is recommended

- Azithromycin should be used with caution in patients predisposed to QT interval prolongation or in patients taking

other medications known to prolong the QT interval.

- *Clostridium difficile* associated diarrhea (CDAD) has been reported with use of azithromycin and may range in

severity from mild diarrhea to fatal colitis. If CDAD is suspected or confirmed, ongoing antibiotic use may need to

be discontinued.

Pregnancy & Lactation:

Azithromycin should only be used in pregnancy & lactating women where adequate alternatives are not available.

DRUG INTERACTIONS:

Antacids: In patients receiving both azithromycin and antacids, Azithromycin should be taken at least 1 hour before

or 2 hours after the antacid.

Cyclosporine: If co-administration of these drugs is necessary, cyclosporine levels should be monitored and the dose

adjusted accordingly.

Theophylline: Theophylline levels may be increased in patients taking azithromycin.

Coumarin-type oral anticoagulants: Consideration should be given to the frequency of monitoring prothrombin

time, when azithromycin is used in patients receiving coumarin-type oral anticoagulants.

Digoxin: In patients receiving concomitant azithromycin, a related azalide antibiotic and digoxin, the possibility of

raised digoxin levels should be borne in mind.

ADVERSE REACTIONS:

Very Common:

Diarrhea, abdominal pain, nausea and flatulence.

Common:

Lymphocyte count decreased, eosinophil count increased, anorexia, dizziness, headache, deafness, vomiting,

dyspepsia, rash, fatigue and blood bicarbonate decreased.

Uncommon:

Oral candidiasis, vaginal infection, hypersensitivity, nervousness, insomnia, hearing impaired, constipation,

abnormal liver enzymes, Steven-Johnson syndrome, photosensitivity reaction, urticaria, chest pain and oedema.

Rare:

Thrombocytopenia, hemolytic anemia, agitation and renal failure.

OVERDOSAGE:

The typical symptoms of an overdose with macrolide antibiotics include reversible loss of hearing, severe nausea,

vomiting and diarrhea. In the event of overdose, the administration of medical charcoal and general symptomatic

treatment and supportive measures are indicated as required.

INSTRUCTION:

- Store below 30°C.

- Protect from light & moisture.

- Keep out of reach of children.

To be sold on prescription of a registered medical practitioner only.

HOW SUPPLIED:

TWEET (Azithromycin) 500mg Tablets are available in pack of 6's.

TWEET (Azithromycin) 250mg Capsules are available in pack of 10's.

TWEET (Azithromycin) 200mg/5mL Powder for Oral Suspension is

available in pack size of 15mL PET Bottle.

**SIGMA
PHARMA**

Manufactured By:
SIGMA PHARMA (International Private Limited.)
E50 North Western Industrial Zone
Port Qasim Authority, Karachi-Pakistan
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