

Composition:

ARISTOMOX® 250 Capsule: Each capsule contains Amoxicillin Trihydrate BP 287.50 mg equivalent to Amoxicillin 250 mg.

ARISTOMOX® Powder for Suspension: After reconstitution each 5 ml contains Amoxicillin Trihydrate BP 143.50 mg equivalent to Amoxicillin 125 mg.

Pharmacology:

Amoxicillin is a semi-synthetic antibiotic, an analog of ampicillin, with a broad spectrum of bactericidal activity against many gram-positive and gram-negative microorganisms. Amoxicillin is bactericidal against susceptible organisms during the stage of active multiplication. It acts through the inhibition of biosynthesis of cell wall mucopeptides.

Indications:

ARISTOMOX[®] is indicated in the following bacterial infections: Respiratory tract infections, otitis media, enteric fever, urinary tract infections, gram-negative septicemia, gonorrhea, other surgical infections, prevention of infective endocarditis.

Dosage & Administration:

Usual oral dose: 250 to 500 mg every 8 hours. Children up to 10 years: 125 to 250 mg every 8 hours. Under 20 kg body weights: 20 to 40 mg/kg/day in divided doses every 8 hours. Infants less than 3 months: Maximum dose should be 30 mg/kg/day in divided doses every 12 hours.

Special Dosage: Uncomplicated gonorrhea: A single dose of 3 g with probenecid 1 g. Dental abscess: 3 g repeated after 8 hours. Uncomplicated acute urinary tract infections: 3 g repeated after 10-12 hours. Prophylaxis of endocarditis: 2 or 3 g 1 hour before dental procedures under local or no anesthesia. Severe or recurrent respiratory tract infections: 3 g twice daily. Otitis media: children 3-10 years, 750 mg twice daily for 2 days. *H. pylori* eradication: In combination with metronidazole or clarithromycin and a bismuth compound or an antisecretory drug usual doses of Amoxicillin are 750 mg or 1g twice daily or 500 mg three times daily.

Contraindications:

Amoxicillin is contraindicated in individuals with a history of an allergic reaction to any of the penicillins.

Side Effects:

Nausea, vomiting, diarrhoea, rashes (discontinue treatment), rarely antibiotic associated colitis.

Warning:

Superinfections may appear with the use of broad-spectrum antibiotics. Treatment should be discontinued if any superinfection appears with the use of Amoxicillin and necessary treatment should be taken for the superinfection.

Storage:

- Store below 30°C, keep in dry place & protect from light.
- · Keep out of the reach of children.

Packing:

ARISTOMOX® 250 Capsule: Each box containing 120 capsules in blister pack.
ARISTOMOX® 500 Capsule: Each box containing 120 capsules in blister pack.
ARISTOMOX® Powder for Suspension: Each bottle containing dry powder for reconstitution of 100 ml oral suspension.

Manufactured for:

ARISTOPHARMA LTD.
Shampur-Kadamtali I/A, Dhaka-Bangladesh
by Apex Pharma Limited, Shafipur, Kaliakair, Gazipur, Bangladesh.