For the use of only a Registered Medical Practitioner or a Hospital or a Laboratory

Not to be sold by retail without the prescription of a Registered Medical Practitioner

Prescribing Information

1. Generic Name

Amoxycillin Trihydrate Dispersible Tablets IP
(Brand Name: BLUMOX® 250 DT)

Amoxycillin Capsules IP
(Brand Name: BLUMOX® 500 Capsules)

2. Qualitative and Quantitative Composition

BLUMOX 250 DT
Each dispersible uncoated tablet contains:
Amoxycillin Trihydrate IP
equivalent to Amoxycillin ……..…… 250 mg.
Excipients: …… q.s.

BLUMOX 500 Capsules
Each hard gelatin capsule contains:
Amoxycillin Trihydrate IP
equivalent to Amoxycillin ……..… 500 mg.
Colours used in Capsule Shape – Sunset Yellow FCF. Quinoline Yellow WS, Titanium Dioxide IP.
Methylparaben, Propylparaben used as Antimicrobial preservatives.

3. Dosage Form and Strength

Dosage Form: Dispersible Tablets (DT) and Capsules.
Dosage Strength: Amoxycillin 250 mg per tablet and 500 mg per capsule.

4. Clinical Particulars

4.1 Therapeutic Indication

Amoxycillin is indicated in the treatment of following infections when caused by susceptible bacteria:

- Ear, Nose and Throat infections
- Respiratory tract infections
- Skin and skin structure infections
- Genitourinary tract infections
- Gonorrhoea, Acute uncomplicated (anogenital and urethral) infections

4.2 Posology and Method of Administration

For oral administration.

Adults

Mild to moderate infections: Amoxycillin 250 mg every 8 hours or 500 mg every 12 hours.
Severe infections: Amoxycillin 500 mg every 8 hours or 875 mg every 12 hours
Gonorrhoea, Acute uncomplicated infections: 3 gm as single dose
Or, as prescribed by the physician.

Paediatrics aged > 3 months (weighing < 40 kg)

Mild to moderate infections: 20 mg/kg/day in divided doses every 8 hours or 25 mg/kg/day in divided doses every 12 hours
Otitis media and Lower respiratory tract infections: 40 mg/kg/day in divided doses every 8 hours or 45 mg/kg/day in divided doses every 12 hours
Severe infections: 40 mg/kg/day in divided doses every 8 hours or 45 mg/kg/day in divided doses every 12 hours

Children weighing 40 kg or more should be dosed according to the adult recommendations.

Neonates and infants aged ≤ 12 weeks (≤ 3 months): Due to incompletely developed renal function affecting elimination of Amoxycillin in this age group, the recommended upper dose of Amoxycillin is 30 mg/kg/day divided every 12 hours.
Or, as prescribed by the physician.

The duration of therapy depends on type and severity of infection. Treatment should not be extended beyond 14 days without review.

Directions for Reconstitution of Dispersible Tablets

BLUMOX 250 Dispersible Tablets should be reconstituted by the addition of an adequate amount of clean potable water (5 to 10 ml) immediately before use. Stir gently until the tablet gets properly dispersed and then swallow.

4.3 Contraindications

Amoxycillin is contraindicated in patients with known hypersensitivity to amoxicillin or to any other beta-lactam antibiotic or to any component of the formulation. It is also contraindicated in individuals who have experienced a serious hypersensitivity reaction (e.g., anaphylaxis or Stevens-Johnson syndrome) to Amoxycillin or to other β-lactam antibiotics in the past.

4.4 Special Warnings and Precautions for Use

Before initiating therapy with Amoxycillin, careful enquiry should be made concerning previous hypersensitivity reactions to penicillins and cephalosporins. Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients on penicillin therapy. These reactions are more likely to occur in individuals with a history of hypersensitivity to beta-lactam antibiotics.

Clostridium difficile-associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including Amoxycillin, and may range in severity from mild diarrhea to fatal colitis. If CDAD is suspected or confirmed, ongoing antibiotic use not directed against *C. difficile* may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of *C. difficile*, and surgical evaluation should be instituted as clinically indicated.

Erythematous (morbilliform) rashes have been associated with glandular fever in patients receiving Amoxycillin.

Prolonged use may also occasionally result in overgrowth of non-susceptible organisms.

In patients with reduced urine output, crystalluria has been observed very rarely, predominantly with parenteral therapy. During the administration of high doses of Amoxycillin, it is advisable to maintain adequate fluid intake and urinary output in order to reduce the possibility of Amoxycillin crystalluria.

In patients with renal impairment, the rate of excretion of Amoxycillin will be reduced depending on the degree of impairment and it may be necessary to reduce the total daily unit Amoxycillin dosage accordingly.

Precautions should be taken in premature children and during the neonatal period; renal, hepatic and hematological functions should be monitored.

4.5 Drug Interactions

Probenecid: Probenecid decreases the renal tubular secretion of Amoxycillin. Concurrent use with Amoxycillin may result in increased and prolonged blood levels of Amoxycillin.

Oral Contraceptives: As with other antibiotics, Amoxycillin may affect the gut flora, leading to lower estrogen reabsorption and reduced efficacy of combined oral contraceptives.

Allopurinol: Concurrent administration of allopurinol during treatment with Amoxycillin can increase the likelihood of allergic skin reactions.

Oral Anticoagulants: In the literature there are rare cases of increased international normalized ratio in patients maintained on acenocoumarol or warfarin and prescribed a course of Amoxycillin. If co-administration is necessary, the prothrombin time or international normalized ratio should be carefully monitored with the addition or withdrawal of Amoxycillin.

4.6 Use in Special Populations

Pregnant Women

Pregnancy Category B. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. Limited data on the use of Amoxycillin during pregnancy in humans do not indicate an increased risk of congenital malformations. Amoxycillin may be used in pregnancy when the potential benefits outweigh the potential risks associated with treatment.

Lactating Women

Penicillins have been shown to be excreted in human milk. Amoxycillin use by nursing mothers may lead to sensitization of infants. Caution should be exercised when Amoxycillin is administered to a nursing woman.

Paediatric Patients

Because of incompletely developed renal function in neonates and young infants, the elimination of Amoxycillin may be delayed. Dosing of Amoxycillin should be modified in paediatric patients 12 weeks or younger (≤3 months) (For dosage, please refer 'Posology and Method of Administration' section)

In recommended dosage, Amoxycillin is safe for use in children above 3 months.

For younger children, it is recommended to use paediatric formulations (such as suspension) and dosage should be administered based on per kg body weight (For dosage, please refer 'Posology and Method of Administration' section)

Geriatric Patients

Usually, no dose adjustment is considered necessary in elderly patients with normal renal function. Amoxycillin is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Renal Impairment Patients

Amoxicillin is primarily eliminated by the kidney and dosage adjustment is usually required in patients with severe renal impairment glomerular filtration rate (GFR) < 30 mL/min. Severely impaired patients with a GFR of < 30 mL/min should not receive a 875 mg dose.

Dosage in patients with a glomerular filtration rate (GFR) of 10 to 30 ml/min should receive 500 mg or 250 mg every 12 hours. Patients with a GFR less than 10 ml/min and hemodialysis patients should receive 500 mg or 250 mg every 24 hours, depending on severity of the infection.

Hepatic Impairment Patients

Dosage should be used with caution and hepatic function monitored at regular intervals.

4.7 Effect on Ability to Drive and Use Machines

No studies on the effects on the ability to drive and use machines have been performed. However, undesirable effects may occur (e.g. allergic reactions, dizziness, convulsions), which may influence the ability to drive and use machines.

4.8 Undesirable Effects

The most common adverse reactions reported with Amoxycillin are diarrhea, rash, vomiting, and nausea. Other less frequently or rarely reported adverse reactions include the following:

- Infections and Infestations: Mucocutaneous candidiasis.
- Gastrointestinal: Black hairy tongue, and hemorrhagic/pseudomembranous colitis. Onset of pseudomembranous colitis symptoms may occur during or after antibacterial treatment
- Hypersensitivity Reactions: Anaphylaxis, serum sickness–like reactions, erythematous maculopapular rashes, erythema multiforme, Stevens-Johnson syndrome, exfoliative dermatitis, toxic epidermal necrolysis, acute generalized exanthematous pustulosis, hypersensitivity vasculitis and urticaria.

- Liver: A moderate rise in AST and/or ALT, hepatic dysfunction including cholestatic jaundice, hepatic cholestasis and acute cytolytic hepatitis.
- Renal: Crystalluria.
- Hemic and Lymphatic Systems: Anemia, including hemolytic anemia, thrombocytopenia, thrombocytopenic purpura, eosinophilia, leukopenia, and agranulocytosis. These reactions are usually reversible on discontinuation of therapy and are believed to be hypersensitivity phenomena.
- Central Nervous System: Reversible hyperactivity, agitation, anxiety, insomnia, confusion, convulsions, behavioral changes, and/or dizziness.
- Miscellaneous: Tooth discoloration (brown, yellow, or gray staining). Discoloration was reduced or eliminated with brushing or dental cleaning in most cases.

4.9 Overdose

Gastrointestinal effects such as nausea, vomiting and diarrhoea may be evident and should be treated symptomatically with attention to the water/electrolyte balance. Crystalluria, in some cases leading to renal failure, has also been reported after Amoxycillin overdose in adult and pediatric patients. In case of overdose, adequate fluid intake and diuresis should be maintained to reduce the risk of Amoxycillin crystalluria. Renal impairment appears to be reversible with cessation of drug administration. High blood levels may occur more readily in patients with impaired renal function because of decreased renal clearance of Amoxycillin. Amoxycillin may be removed from circulation by hemodialysis.

5. Pharmacological Properties

5.1 Mechanism of Action

Amoxycillin is a penicillin class of beta-lactam antibiotics. Amoxycillin acts through the inhibition of cell wall biosynthesis during the stage of active multiplication that leads to the death of the bacteria - bactericidal action. Amoxycillin is semi-synthetic penicillin that inhibits one or more enzymes (often referred to as penicillin-binding proteins, PBPs) in the biosynthetic pathway of bacterial peptidoglycan, which is an integral structural component of the bacterial cell wall. Inhibition of peptidoglycan synthesis leads to weakening of the cell wall, which is usually followed by bacterial cell lysis and death.

5.2Pharmacodynamic Properties

Amoxycillin has been shown to be active against most isolates of the bacteria mentioned below, both *in vitro* and in clinical infections.

Gram-Positive Bacteria

- *Enterococcus faecalis.*
- *Staphylococcus species.*
- *Streptococcus pneumoniae.*
- *Alpha and β-hemolytic streptococci.*

Gram-Negative Bacteria

- *Escherichia coli.*
- *Haemophilus influenza.*
- *Neisseria gonorrhoeae.*
- *Proteus mirabilis.*
- *Helicobacter pylori.*

5.3 Pharmacokinetic Properties

Absorption: The absolute bioavailability of Amoxycillin depends on the dose and ranges between 75 and 90%. In the dose range between 250 mg and 750 mg the bioavailability is linearly proportional to the dose. At higher doses the extent of absorption decreases. The absorption is not affected by concomitant food intake.

Distribution: Protein binding for Amoxycillin is approximately 17%. Therapeutic drug levels are rapidly achieved in serum, lung tissue, bronchial secretions, middle ear fluid, bile and urine. Amoxycillin crosses the placenta and a small percentage is excreted into the breast milk.

Metabolism and Excretion: The main route of excretion of Amoxycillin is the kidney. About 60 to 80% of oral dose of Amoxycillin are excreted in unchanged active form in the urine within 6 hours of administration, and a small fraction is excreted in the bile. Approximately 7 to 25% of the administered dose is metabolised to inactive penicilloic acid. The serum half-life in patients with normal renal function is approximately 1 to 1.5 hour. In patients with end-stage renal failure the half-life ranges between 5 to 20 hours.

6. Nonclinical Properties

6.1 Animal Toxicology

Non-clinical data reveal no hazard for humans based on studies of safety pharmacology, repeated dose toxicity, genotoxicity and toxicity to reproduction and development. Carcinogenicity studies have not been conducted with Amoxycillin.

7. Description

BLUMOX 250 Tablets are white round, flat, beveled edge having light creamish spots with one side break line and other side plain.

BLUMOX 500 Capsules are Golden Yellow/Golden Yellow coloured size “0” hard gelatin capsules containing white granular powder.

BLUMOX 250 Dispersible Tablets contain 250 mg of Amoxycillin whereas BLUMOX 500 Capsule contains 500 mg of Amoxycillin for oral administration in adults and adolescents.

Amoxycillin is a semisynthetic antibiotic with a broad spectrum of bactericidal activity against many Gram-positive and Gram-negative microorganisms.

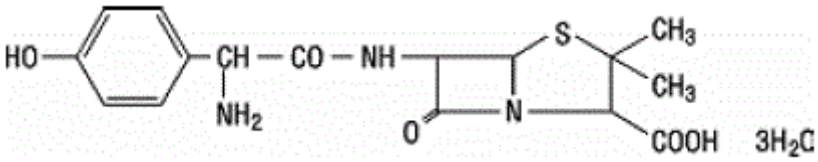
Amoxycillin trihydrate is crystalline and off-white in color.

Molecular Weight: 419.45 g/mol.

Molecular Formula: C16H19N3O5S•3H2O.

Chemical Name: (2S,5,R,6,R)-6-[(,R)-(-)-2-amino-2-(p-hydroxyphenyl)acetamido]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid trihydrate.

Structural Formula:



Inactive ingredients (excipients) of BLUMOX 250 DT contain Saccharin Sodium, Colloidal Silicon Dioxide, Sodium Starch Glycolate, Flavour Lemon Dry, Magnesium Stearate, Talcum & Microcrystalline Cellulose.

Inactive ingredients (excipients) of BLUMOX 500 Capsule contain Talcum, Magnesium Stearate & Hard Gelatin Capsules.

8. Pharmaceutical Particulars

8.1 Incompatibilities

Not applicable.

8.2 Shelf-life

BLUMOX 250 DT: 24 Months
BLUMOX 500 Capsules: 24 Months

8.3 Packaging Information

BLUMOX 250 DT: 15 tablets per strip.
BLUMOX 500 Capsules: 10 capsules per blister.

8.4 Storage and Handling Instructions

BLUMOX 250 DT: Store protected from light and moisture at a temperature not exceeding 30°C.
BLUMOX 500 Capsules: Store protected from light and moisture at temperature not exceeding 30°C.

9. Patient Counseling Information

Administration Instructions

- Patients should be counseled that antibacterial drugs should only be used to treat bacterial infections. Not to use this medicine to treat infections caused by viruses.
- Patients should be told that although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may decrease the effectiveness of the treatment and increase the likelihood that bacteria will develop resistance to the antibiotic and may not be treatable by amoxycillin or other antibacterial drugs in the future.
- Advise patients that diarrhea is a common problem caused by antibacterial drugs which usually ends when the antibacterial drug is discontinued.

- Sometimes after starting treatment with antibacterial drugs, patients can develop watery and bloody stools (with or without stomach cramps and fever) even as late as two or more months after having taken the last dose of the antibacterial drug. If this occurs, patients should contact their Doctor as soon as possible.
- BLUMOX contains Amoxycillin which is a penicillin class of drug that can cause allergic reactions in some individuals. If patient has history of allergic reaction to any penicillin class of drug in the past, BLUMOX should be strictly avoided.

10. Details of Manufacturer

Malik Life Science Pvt. Ltd.
(A subsidiary of Akums Drugs & Pharmaceuticals Ltd.)
Plot No.-16, Vardhman Indl Estate, N.H. 58, Haridwar – 247 667, Uttarakhand.

11. Details of Permission or License Number with Date

Blumox 250 DT – Manufacturing License No. 48/UA/SC/P-2013. Date of Product Permission – 13/11/2014

Blumox 500 Capsules - Manufacturing License No. 48/UA/SC/P-2013. Date of Product Permission – 13/11/2014

12. Date of Revision

August 2024.

Marketed by:
BLUE CROSS LABORATORIES PVT LTD.
A-12, M.I.D.C., NASHIK-422 010.
Regd. Off.: Peninsula Chambers, G. K. Marg, Mumbai-400 013.