

AMOXICILLIN CAPSULES BP

Pulmoxyl® -500 Capsules

COMPOSITION:

Each 500 mg capsule contains: Amoxycillin Trihydrate BP equivalent to Amoxycillin 500mg

DESCRIPTION:

Pulmoxyl 500: "Maroon/Yellow '0' size capsules with 'AMOXI' printed on cap & '500' on body in black ink containing white or almost white crystalline powder inside".

PHARMACOLOGICAL ACTION: Amoxycillin is a semisynthetic antibiotic, an analogue of ampicillin with a broad spectrum bactericidal activity against many gram-positive and gram-negative organisms. It exhibits bactericidal action against susceptible organisms during the stage of active multiplication and acts through the inhibition of biosynthesis of cell. It is not effective against penicillinase producing bacteria.

INDICATIONS: Treatment of infections due to susceptible strains of the following:

Gram-negative organisms: H Influenzae, E.coli, P mirabilis, N. Gonorrhoeae.

Gram-positive organisms: Streptococci, D. pneumoniae and non-penicillina seproducing staphylococci.

CONTRAINDICATIONS: History of allergic reactions to penicillins.

PRECAUTIONS AND WARNINGS:

Serious and occasionally fatal hypersensitivity reactions (including anaphylactoid and severe cutaneous adverse reactions) have been reported in patients on penicillin therapy. These reactions are more likely to occur in individuals with a history of penicillin hypersensitivity. Hence, careful enquiry about previous hypersensitivity reactions should be made before administering amoxicillin. If an allergic reaction occurs, Pulmoxyl must be discontinued and appropriate alternative therapy instituted. Serious anaphylactic reactions require immediate emergency treatment with adrenaline. Oxygen, intravenous steroids and airway management (including intubation) may also be required. As with any potent drug, periodic assessment of renal, hepatic and hematopoietic function should be made during prolonged therapy. This product contains Tartrazine.

USAGE IN PREGNANCY: Safety for usage in pregnancy has not been established.

ADVERSE REACTIONS: Nausea, vomiting, diarrhoea, erythematous maculopapular rashes, erythema multiforme, Stevens-Johnson Syndrome, toxic epidermal necrolysis, urticaria, anemia, thrombocytopenia, eosinophilia, leucopenia and agranulocytosis, agitation, anxiety, insomnia, confusion, and dizziness have been reported.

Skin and subcutaneous tissue disorders

Very rare: Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)

Nervous system disorders

Very rare: Aseptic meningitis

DRUG INTERACTIONS/COMPATIBILITIES: The excretion of amoxycillin can be delayed by concurrent administration of Probenecid. When administered concurrently interactions may occur with chloramphenicol, erythromycins and tetracyclines.

DOSAGE: Adults: 250mg every 8 hours.

Children: 20 mg/kg/day in divided doses every 8 hours. In severe infections the above dose may be doubled.

Gonorrhoea: Adults: 3 grams as single oral dose.

Except for gonorrhoea, treatment should be continued for a minimum of 48 to 72 hours after the patient becomes asymptomatic.

LIST OF EXCIPIENTS: Magnesium stearate, Talc, Sodium lauryl sulphate, and Empty Hard Gelatine capsule

Ingredients of Capsule:

Cap – Brilliant Blue FCF, Carmoisine, Sunset Yellow FCF, Titanium Dioxide

Body – Iron Oxide Yellow, Titanium Dioxide

Ingredient of Printing Ink: Black Marking Solution

Shellac, Dehydrated Alcohol, Butyl Alcohol, Propylene Glycol, Black Iron Oxide, Purified Water, Isopropyl Alcohol

PRESENTATION: Blister pack of 10x10's, 50x10's, Container of 500's and 1000's.

Not all presentations may be available locally, or equivalent, as the 'Container of 500's and 1000's' is not registered locally.

STORAGE: Store at or below 30°C.

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Manufactured by:

MICRO LABS LIMITED

Plot No. 16, Veerasandra Industrial Area,
Anekal Taluk, Bangalore-560 100. INDIA

Pulmoxyl®-500
SIN 11190P

® Regd. Trade Mark