

Flamox[®] (Capsules)

Flucloxacillin Sodium
Amoxicillin Trihydrate

Antibacterial

Flamox[®] Capsules 500mg

PRESENTATION:

Flamox[®] Capsules 500mg: White, granular free flowing powder filled in Dark blue/Grey hard gelatin capsule printed 'COSMOS/FLAMOX' on body and cap. 500

Each capsule contains: Flucloxacillin Sodium equivalent to Flucloxacillin 250mg and Amoxicillin Trihydrate equivalent to Amoxicillin 250mg.

CLINICAL PHARMACOLOGY:

Flucloxacillin is an isoxazolyl penicillin. It has bactericidal action against Gram-positive bacteria, Gram-negative cocci, some other Gram-negative bacteria, spirochaetes and actinomycetes. It exerts its killing action on growing and dividing bacteria by inhibiting bacterial cell wall synthesis, although the mechanisms involved are still not precisely understood. Bacterial cell walls are held rigid and protected against osmotic rupture by peptidoglycan. Flucloxacillin inhibits the final cross-linking stage of peptidoglycan production by binding to and inactivating transpeptidases, penicillin-binding proteins on the inner surface of the bacterial cell membrane. Flucloxacillin is resistant to staphylococcal penicillinase.

Amoxicillin is a beta-lactam antibiotic. It is bactericidal and has a similar mode of action to that of Flucloxacillin but has an aminopenicillin with an amino group side chain attached to the basic penicillin structure. Amoxicillin penetrates the outer membrane of some Gram-negative bacteria and has a broader spectrum of activity.

PHARMACOKINETICS:

Flucloxacillin Sodium is better absorbed from the gastro-intestinal tract but absorption is also reduced by the presence of food in the stomach. It is reported to have a plasma half-life of approximately 1 hour. The half-life is prolonged in neonates. Flucloxacillin is metabolised to a limited extent and the unchanged drug and metabolites are excreted in the urine by glomerular filtration and renal tubular secretion. About 50% of a dose by mouth is excreted in the urine within 6 hours. Only small amounts are excreted in the bile.

Amoxicillin is resistant to inactivation by gastric acid secretions. Peak plasma-amoxicillin concentrations of about 5µg per mL have been observed in 1 to 2 hours after a dose of 250mg. About 20% is bound to plasma proteins in the circulation and plasma half-lives of 1 to 1.5 hours have been reported. The half-life may be prolonged in neonates, the elderly and patients with renal impairment; in severe renal impairment the half-life may be 7 to 20 hours. Amoxicillin is widely distributed at varying concentrations in body tissues and fluids. It crosses the placenta; small amounts are distributed into breast milk. Amoxicillin is metabolised to a limited extent to penicilloic acid and is excreted in the urine.

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USES:

Flamox[®] is used for the treatment of severe infections caused by organisms sensitive to either or both active ingredients; chest infections, ENT infections, skin infections and soft tissue infections.

DOSAGE AND ADMINISTRATION:

Adults: The usual oral dose is 500 mg every 8 hours.

CONTRA-INDICATIONS AND WARNINGS:

Patients known to be hypersensitive to penicillins should be given an antibiotic of another class. It should be given with caution to patients with a history of allergy especially to drugs. Care is necessary if very high doses of penicillin are given especially if renal function is poor because of the risk of neurotoxicity.

Adverse Effects:

The most common adverse effects of Flucloxacillin and Amoxicillin are hypersensitivity reactions especially skin rashes, anaphylaxis occasionally occurs and has sometimes been fatal. Gastro-intestinal effects (e.g. nausea, diarrhoea) has been reported.

Overdosage:

Problems of overdosage are unlikely to occur; if encountered they may be treated symptomatically.

Interactions:

Probenecid prolongs the half-life of Flucloxacillin and Amoxicillin by competing with them for renal tubular secretion. Flucloxacillin and Amoxicillin may also interact with bacteriostatic antibacterials such as chloramphenicol and tetracyclines and may be incompatible *in vitro* with other drugs, including a number of other antibacterials.

PHARMACEUTICAL PRECAUTIONS:

Store in a dry place below 25°C. Protect from light. Keep all medicines out of the reach of children.

LEGAL CATEGORY:

Prescription Only Medicine (POM)

Mfg. Lic. No.: 69/MD/AP/99/F/R

Ref. No.: INS114/VC/02.18

[®] Regd. TM



Manufactured for:

Cosmos Limited, Rangwe Rd; Off Lunga Lungu Rd, Nairobi, Kenya.

Manufactured by:

Yeluri Formulations Pvt. Ltd.

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Sangareddy district, 502 325,

Telangana, India.