

GrumoxTM-CV 625

(Amoxicillin & Potassium Clavulanate Tablets)

Composition:

Each film coated tablet Contains:

Amoxicillin Trihydrate I P
Equivalent to Amoxicillin500 mg
Potassium Clavulanate Diluted IP
Equivalent to Clavulanic Acid..... 125 mg

Clinical Pharmacology:

Amoxicillin:

Amoxicillin is a broad-spectrum beta-lactam antimicrobial originally derived from penicillin. It is a bactericidal agent that targets and kills bacteria by inhibiting the biosynthesis of the peptidoglycan layer of the bacterial cell wall. This layer makes up the outermost portion of the cell wall and is responsible for the structural integrity of the cell. Peptidoglycan synthesis involves the facilitation of DD-transpeptidases, which are a type of penicillin-binding protein (PBP). Amoxicillin works by binding to these PBPs and inhibiting peptidoglycan synthesis, which interrupts the construction of the cell wall and ultimately leads to the destruction, or lysis, of the bacteria.

Clavulanic acid:

Clavulanic acid is a beta-lactamase inhibitor often used in conjunction with amoxicillin to broaden its spectrum further and combat resistance. It has little to no antimicrobial activity of its own and instead works by preventing bacterial destruction of beta-lactams. Over the years, certain bacteria have evolved to develop resistance to standard beta-lactam antimicrobials through the production of enzymes called beta-lactamases. These enzymes target and hydrolyze the beta-lactam ring, which is necessary for penicillin-like antimicrobials to work. Clavulanic acid prevents this degradation by binding and deactivating the beta-lactamases, thus restoring the antimicrobial effects of amoxicillin.

Advantage of Grumox-CV:

The oral bioavailability of amoxicillin is 74 to 92%, whereas that of clavulanic acid is more variable, ranging between 31 to 99%. Compared to international brand equivalence reference tablet amoxicillin + clavulanic solutab showed less variation in the clavulanic acid parameters both in respect of AUC & Cmax.

Indications:

Amoxicillin-clavulanate is one of the most frequently used antimicrobials in emergency departments and primary care offices throughout the country. It is a combination of two separate drugs: amoxicillin and clavulanic acid. Amoxicillin is a penicillin derivative and has similar activity against gram-positive and gram-negative bacteria, including *Enterococcus* species, *Listeria monocytogenes*, *Streptococcus* species, *Haemophilus influenzae*, *Moraxella catarrhalis*, *Corynebacterium diphtheriae*, *Escherichia coli*, *Klebsiella pneumoniae*, *Salmonella* spp., *Shigella* spp., and *Borrelia* species. Furthermore, with the addition of clavulanic acid, the spectrum is increased to include all beta-lactamase-producing strains of the previously mentioned organisms, as well as broadening the coverage to include methicillin sensitive *Staphylococcus aureus* (MSSA), *Neisseria* species, *Proteus* species, *Pasteurella multocida*, and *Capnocytophaga canimorsus*, among others. Amoxicillin-clavulanate has approval for the treatment of aspiration pneumonia, community-acquired pneumonia, acute bacterial rhinosinusitis, urinary tract infections, acute otitis media, and skin and soft tissue infections. Off-label uses include the treatment of human or animal bite wounds, group A streptococcal infections, impetigo, acute exacerbations of chronic obstructive pulmonary disease and bronchiectasis, diabetic foot infections, odontogenic infections, and peritonsillar cellulitis/abscess.

Contraindications:

Contraindicated in patients with a history of hypersensitivity to beta-lactams, e.g. penicillins and cephalosporins. It is contraindicated in patients with a previous history of amoxy-clav associated jaundice/hepatic dysfunction.

Special Warnings and Precautions:

For Use Before initiating therapy careful enquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins, or other allergens. Serious and occasionally fatal hypersensitivity reactions (including anaphylactoid and severe cutaneous adverse reactions) have been reported in patients on penicillin therapy.

Drug Interactions:

Concomitant use of probenecid is not recommended. Probenecid decreases the renal tubular secretion of amoxicillin. Concomitant use of allopurinol during treatment with amoxicillin can increase the likelihood of allergic skin reactions. May affect the gut flora, leading to lower oestrogen reabsorption and reduced efficacy of combined oral contraceptives.

For Therapeutic Use.

Route of administration: Oral.

Type of tablet: Film coated tablet.

Flavour: Delicious Vanilla.

Dosage: As directed by the Physician.

Storage: Store protected from light & moisture, at a temperature not exceeding 25°C.

SCHEDULE H PRESCRIPTION DRUG CAUTION- Not to be sold by retail without the Prescription of a Registered Medical Practitioner.

Presentation: Grumox- CV 625 TAB available as 10x10 Tablets

Marketed By:



EPIONE PHARMACEUTICALS PVT.LTD.

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