

AMPOXIN CV

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

Abbreviated Prescribing information for **AMPOXIN** (Amoxicillin and Potassium Clavulanate Tablets I.P.) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

Amoxicillin is a semisynthetic penicillin (beta-lactam antibiotic) 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 cell lysis and death.

Amoxicillin is susceptible to degradation by beta-lactamases produced by resistant bacteria and therefore the spectrum of activity of amoxicillin alone does not include organisms which produce these enzymes.

Clavulanic acid is a beta-lactam structurally related to penicillins. It inactivates some beta-lactamase enzymes thereby preventing inactivation of amoxicillin. Clavulanic acid alone does not exert a clinically useful antibacterial effect.

INDICATIONS:

It is indicated in the treatment of acute bacterial sinusitis, acute otitis media, community acquired pneumonia, cystitis, pyelonephritis, skin and soft tissue infections in particular cellulitis, animal bites, severe dental abscess with spreading cellulitis, Bone and joint infections, in particular osteomyelitis.

DOSAGE AND ADMINISTRATION: Dosage: As directed by the Physician.

- **CONTRAINDICATION:** Hypersensitivity to the active substances, to any of the penicillins or to any of the excipients. History of a severe immediate hypersensitivity reaction (e.g. anaphylaxis) to another beta-lactam agent (e.g. a cephalosporin, carbapenem or monobactam) History of jaundice/hepatic impairment due to amoxicillin/clavulanic acid

WARNINGS & PRECAUTION: Enquiry should be done concerning previous hypersensitivity reactions to penicillins, cephalosporins or other beta-lactam agents. As medicine contains potassium care must be taken in patients with reduced kidney function or patients on a controlled potassium diet. Convulsions may occur in patients with impaired renal function or in those receiving high doses. Concomitant use of allopurinol during treatment with amoxicillin can increase the likelihood of allergic skin reactions. Hepatic events have been reported predominantly in males and elderly patients and may be associated with prolonged treatment. In patients with reduced urine output, crystalluria has been observed very rarely, predominantly with parenteral therapy [Refer Prescribing information for more details.

] **DRUG INTERACTIONS:** Concurrent administration of *Oral anticoagulants like warfarin* may the prothrombin time. In patients receiving mycophenolate mofetil, reduction in pre-dose concentration of the active metabolite mycophenolic acid (MPA) of approximately 50% has been reported following commencement of oral amoxicillin plus clavulanic acid. The change

in pre-dose level may not accurately represent changes in overall MPA exposure [Refer Prescribing information for more details]

ADVERSE REACTIONS: Infections and infestations Overgrowth of non-susceptible organisms. Blood and lymphatic system disorders: Reversible leucopenia (including neutropenia), Thrombocytopenia, Reversible agranulocytosis, Immune system disorders: Angioneurotic oedema, Nervous system disorders; Dizziness, Headache, Reversible hyperactivity, Gastrointestinal disorders: Diarrhoea, Nausea, exposure [Refer Prescribing information for more details]

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(Additional information is available on request)