

## AMPOXIN CV DRY SYRUP

**To be sold by retail on the prescription of R.M.P only.**

Abbreviated Prescribing information for AMPOXIN CV DRY SYRUP (Amoxicillin and Potassium Clavulanate Oral Suspension)

[Please refer the complete prescribing information available at [www.torrentpharma.com](http://www.torrentpharma.com)]

### PHARMACOLOGICAL PROPERTIES:

**Mechanism of action:** 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 and 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.

**DOSAGE AND ADMINISTRATION:** This product is for Paediatric use only. It should be used in paediatric patients less than 20 kg body weight only, Dosage should be taken as directed by your Physician, Direction for reconstitution: Shake the bottle to loosen powder. Slowly add water provided with this pack (about 20 ml) and shake vigorously. Adjust the volume up to mark by adding remaining water if necessary. This makes 30ml of suspension. Consume within one week after reconstitution. Store the reconstituted suspension in refrigerator when not in use.

**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 & PRECAUTIONS:** Talk to your doctor before taking AMPOXIN CV Dry Syrup, If you suffer from Liver and kidney problems, follow your doctor's instructions, Antibacterial drugs including AMPOXIN CV Dry Syrup should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold), 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 (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by AMPOXIN CV Dry Syrup or other antibacterial drugs in the future.

**DRUG INTERACTION:** It can interact with Oral anticoagulants (eg. acenocoumarol, warfarin), Methotrexate, Probenecid, Mycophenolate Mofetil and Certain Drug/Laboratory Test Interactions.

**ADVERSE REACTIONS:** Undesirable effects may occur like mucocutaneous candidosis, overgrowth of non-susceptible organisms, reversible leucopenia (including neutropenia), thrombocytopenia, reversible agranulocytosis, haemolytic anaemia, prolongation of bleeding time and prothrombin time, anaphylaxis, serum sickness-like syndrome, hypersensitivity vasculitis, dizziness, headache, reversible hyperactivity, convulsions, aseptic meningitis, diarrhoea, nausea, vomiting, indigestion, antibiotic-associated colitis, black hairy tongue, tooth discolouration, hepatobiliary disorders, rises in ast and/or alt, hepatitis, cholestatic jaundice,

skin rash, pruritus, urticaria, erythema multiforme, drug reaction with eosinophilia and systemic symptoms (dress), stevens-johnson syndrome, toxic epidermal necrolysis, bullous exfoliative-dermatitis, acute generalised exanthemous pustulosis (agep), interstitial nephritis.

**MARKETED BY:**

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**IN/ AMPOXIN CV Dry Syrup 228.5 mg/5 ml/MAY-2021/02/ABPI**

(Additional information is available on request)