AMPOXIN

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

Abbreviated Prescribing information for **AMPOXIN** (Ampicillin and Cloxacillin Capsules) [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

Ampicillin

Ampicillin is in the penicillin group of beta-lactam antibiotics and is part of the amino penicillin family. It is roughly equivalent to amoxicillin in terms of activity. Ampicillin is able to penetrate Gram-positive and some Gram-negative bacteria. It differs from penicillin G, or Benzylpenicillin, only by the presence of an amino group. This amino group, present on both ampicillin and amoxicillin, helps these antibiotics pass through the pores of the outer membrane of Gram-negative bacteria, such as *E. coli, Proteus mirabilis, Salmonella enterica*, and *Shigella*.

Ampicillin acts as an irreversible inhibitor of the enzyme transpeptidase, which is needed by bacteria to make the cell wall.[2] It inhibits the third and final stage of bacterial cell wall synthesis in binary fission, which ultimately leads to cell lysis; therefore, ampicillin is usually bacteriolytic

Cloxacillin

Cloxacillin exerts a bacterial action against susceptible microorganisms during the stage of active multiplication. It acts through the inhibition of biosynthesis of cell wall mucopeptides. Cloxacillin demonstrates activity against strains of beta-hemolytic streptococci, pneumococci, penicillin G sensitive staphylococci and, due to its resistance to penicillinase, penicillin G resistant (β-lactamase producing) staphylococci. Cloxacillin displays less intrinsic antibacterial activity and a narrower spectrum than penicillin G.

INDICATIONS:

AMPOXIN is indicated for the treatment of the following infections including mixed Gram-positive (except methicillin-resistant Staphylococcus aureus (MRSA) and methicillin-resistant coagulase-negative staphylococcus (MRCoNS)) and Gram-negative infections:

Surgery*:** post-operative wound infections, post-operative pulmonary infections. ***Respiratory infections: bronchopneumonia, acute exacerbations of chronic bronchitis. ***Obstetrics*:** puerperal fever. Other infections such as septicaemia, bone infections e.g., osteomyelitis, ear, nose and throat infections. Appropriate culture and susceptibility tests should be performed before treatment in order to isolate and identify organisms causing infection and to determine their susceptibility to AMPOXIN. Where treatment is initiated before results are available expert advice should be sought when the local prevalence of resistance is such that the utility of AMPOXIN is questionable (see Pharmacological properties, Pharmacodynamics).

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

CONTRAINDICATION: AMPOXIN should not be given to patients with a history of hypersensitivity to beta-lactam antibiotics (e.g., penicillins, cephalosporins) or excipients. –

AMPOXIN is contraindicated for ocular administration.

WARNINSGS & PRECAUTION: Caution should be observed when administering AMPOXIN to babies whose mothers are hypersensitive to penicillin...Before initiating therapy with AMPOXIN, careful inquiry should be made concerning previous hypersensitivity reactions to beta-lactams. Cross-sensitivity between penicillins and cephalosporins is well documented. .Serious and occasionally fatal hypersensitivity reactions (anaphylaxis) have been reported in patients receiving beta-lactam antibiotics. Although anaphylaxis is more frequent following parenteral therapy, it has occurred in patients on oral penicillins. These reactions are more like to occur in individuals with a history of beta-lactam hypersensitivity. If an allergic reaction occurs, AMPOXIN should be discontinued and the appropriate alternative therapy instituted. All adverse reactions should be treated symptomatically. AMPOXIN should be avoided if infectious mononucleosis and/or acute or chronic leukaemia of lymphoid origin are suspected. The occurrence of a skin rash has been associated with these Conditions following the administration of ampicillin. Prolonged use may occasionally result in overgrowth of non-susceptible organisms. [Refer Prescribing information for more details]

DRUG INTERACTIONS: Probenecid decreases the renal tubular excretion of AMPOXIN. Concurrent use of both drugs may increase and prolonged blood levels of AMPOXIN. Concurrent administration of allopurinol can increase allergic skin reactions. In common with other antibiotics, AMPOXIN may affect the gut flora, leading to lower oestrogen reabsorption and reduced efficacy of combined oral contraceptives. Sulphonamides and acetylsalicylic acid inhibit serum protein binding of cloxacillin in vitro. This may result in increased levels of free cloxacillin in serum in vivo. Bacteriostatic drugs may interfere with the bactericidal action of AMPOXIN. Concurrent administration of allopurinol during treatment with AMPOXIN can increase the likelihood of allergic skin reactions. [Refer Prescribing information for more details]

ADVERSE REACTIONS: Blood and lymphatic system disorders Very rare: Hemolytic anemia, leucopenia, thrombocytopenia, and agranulocytosis **Immune system disorders** Very rare: Anaphylaxis. **Nervous system disorders.** Very rare: Myoclonus and convulsions. **Gastrointestinal disorders** Common: Diarrhoea and nausea Uncommon: Vomiting. **Hepatobiliary disorders** Very rare: Hepatitis and cholestatic jaundice. A moderate and transient increase in transaminases. **Skin and subcutaneous tissue disorders** Common: Skin rash, urticaria, and pruritus. **Renal and urinary disorders** Very rare: Interstitial nephritis

Interstitial nephritis has also been reported as a hypersensitivity reaction (See also Immune system disorders).

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(Additional information is available on request)