

TORMOXIN CLAV

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

Abbreviated Prescribing information for TORMOXIN CLAV [Amoxicillin 200 And Potassium Clavulanate
28.5 mg Oral suspension]

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Tormoxin Clav is a combination of amoxicillin and clavulanic acid. Clavulanic acid itself has only a minimal antibacterial action. However, by binding irreversibly to the beta-lactamases produced by many strains of organisms usually resistant to penicillins, the clavulanic acid protects the amoxicillin from hydrolysis.

INDICATIONS: Tormoxin Clav is indicated for the treatment of infections caused by all organisms sensitive to amoxicillin, as well as those organisms which produce beta-lactamases that are sensitive to clavulanic acid. This includes: Infections of the upper respiratory tract (otitis media). Infections of the lower respiratory tract (bronchitis). Infections of the genito-urinary tract. Infections of the skin and soft tissues.

DOSAGE AND ADMINISTRATION: The presence of food does not affect the absorption of Tormoxin Clav, so that Tormoxin Clav may be taken on a full or empty stomach. In that the incidence of any possible gastrointestinal side-effects is reduced in the presence of food.

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 betalactam agent (e.g. a cephalosporin, carbapenem or monobactam). History of jaundice/hepatic impairment due to amoxicillin/clavulanic acid.

WARNINGS & PRECAUTIONS: When administered to a patient with a penicillin allergy, serious and occasionally fatal hypersensitivity (anaphylactoid) reactions may occur and although this occurs more frequently after intravenous administration, oral therapy has been known to illicit the same response. If an allergic reaction occurs, Tormoxin Clav should be discontinued. Adrenaline, corticosteroids and antihistamines should be used to treat anaphylaxis. Reversible hepatitis and cholestatic jaundice has been reported with amoxicillin and clavulanic combination so that Tormoxin Clav should be used with caution in patients with evidence of hepatic dysfunction.

DRUG INTERACTIONS: Probenecid prolongs the half-life of benzylpenicillin. An increased frequency of skin rashes has been reported in patients receiving amoxicillin together with allopurinol.

ADVERSE REACTIONS: hypersensitivity reactions; especially skin rashes; anaphylaxis, Hepatitis and cholestatic jaundice, Erythema multiforme (including the Stevens-Johnson syndrome), toxic epidermal necrolysis, and exfoliative dermatitis, Skin rashes are however the most common side-effects and are generally either urticarial or maculopapular; the urticarial reactions are typical of penicillin hypersensitivity. The incidence of maculopapular rash is especially high in patients suffering from infectious mononucleosis. Haemolytic anaemia and neutropenia have been reported. Gastro-intestinal adverse effects particularly diarrhoea nausea, vomiting occur quite frequently, a sore mouth or tongue or a black hairy tongue have been reported, usually following administration by mouth and are dose related and can be minimised by administering the medicine at the start of a meal.

MARKETED BY:



Torrent Pharmaceuticals Limited.

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(Additional information is available on request)