AMOCLAN® Intravenous

(Amoxycillin and Clavulanic acid)

ACTION

Amoclan is an antibacterial combination consisting of the semisynthetic broad spectrum antibiotic Amoxycillin and the beta-lactamase enzyme inhibitor Clavulanic acid, which protects Amoxycillin from destruction and subsequent loss of antibacterial activity by the beta-lactamase enzyme produced by many Gram-negative and Gram-positive bacteria. This combination extends the antibacterial spectrum of Amoxycillin to include organisms normally resistant by virtue of their ability to produce beta-lactamase.

INDICATIONS

Amoclan is bactericidal to a wide range of beta-lactamase and non-beta-lactamase producing Gram-positive and Gram-negative bactena including:

Gram-positive: *Staphylococcus aureus, Staphylococcus epidermidis, Streptococcus pyogenes, Streptococcus pneumoniae, Streptococcus viridans, Streptococcus faecalis, Bacillus anthracis, Corynebacterium species, Listeria monocytogenes.* **Gram-negative:** *Haemophilus influenzae, Haemophilus ducreyi, Moraxella catarrhalis, Escherichia coli, Proteus mirabilis, Proteus vulgaris, Klebsiella species, Salmonella species, Shigella species, Bordatella pertussis, Yersinia enterocolitica, Gardnerella vaginalis, Brucella species, Neisseria meningitidis, Neisseria gonorrhoeae, Pasteurella multocida, Campylobacter jejuni (H.pylori), Vibrio cholerae.* **Anaerobes:** *Bacteroides species, including B.fragilis. Clostridium species, Peptococcus species, Peptostreptococcus species.*

Thus, Amoclan Intravenous is indicated for the treatment of:

- Upper respiratory tract infections such as tonsillitis, sinusitis. otitis media.
- Lower respiratory tract infections such as acute and chronic bronchitis, lobar and bronchopneumonia, lung abscess.
- Genito-urinary tract infections such as urethritis, cystitis, pyelonephritis, septic abortion, pelvic infections, gonorrhoea.
- Skin and soft tissue infections such as cellulitis, wound infections, abscesses.
- Bone and joint infections, such as osteomyelitis.
- Other infections such as septicaemia, peritonitis, post-operative infections and intra-abdominal sepsis.
- Intravenous Amoclan ia also indicated for prophylaxis against infections which may be associated with major surgical procedures such as gastrointestinal, pelvic, head and neck, cardiac, renal, joint replacement and biliary tract.

DOSAGE AND ADMINISTRATION

Dosage for treatment of infection:

Adults and children over 12 years:	Usually 1.2 g every 8 hours.In more serious infections, increase frequency to six-hourly intervals.
Children 3 months-12 years:	Usually 30 mg/kg every 8 hours. In more serious infections, increase frequency to six-hourly intervals.
Children 0-3 months:	30 mg/kg every 12 hours in premature infants and in full term infants during the perinatal period, increasing to 8 hours thereafter.

*** Each 30 mg Amoclan contains 25 mg amoxycillin and 5 mg clavulanic acid**

Adult dosage for surgical prophylaxis:

The usual adult dose is 1.2 g Amoclan Intravenous at the induction of anaesthesia. Operations where there is a high risk of infection, e.g. colorectal surgery, may require three, and up to four, doses of 1.2 g Amoclan Intravenous in a 24-hour period. These doses are usually given at 0,8,16 and 24 hours. This regimen can be continued for several days if the procedure has a significantly increased risk of infection. Clear clinical signs of infection at operation will require a normal course of intravenous or oral Amoclan therapy post-operatively.

Dosage in renal impairment:

Adults

Mild impairment (creatinine clearance > 30 ml/min)	Moderate impairment (creatinine clearance 10-30 ml/min)	Severe impairment (creatinine clearance <10 ml/min)
No change in dosage	1.2 g IV stat., followed by 600 mg IV 12 hourly	1.2 g IV stat., followed by 600 mg IV 24 hourly. Dialysis decreases serum concentrations of Amoclan and an additional 600 mg IV dose may be needed to be given during dialysis and at the end of dialysis.

Children

Similar reductions in dosage should be made for children.

Dosage in hepatic impairment: Dose with caution; monitor hepatic function at regular intervals.

Administration: Intravenous Amoclan may be administered either by intravenous injection or by intermittent infusion. It is not suitable for intramuscular administration.

Reconstitution:

600 mg vial : Dissolve in 10 ml sterile water for injection B.P. (Final volume 10.5 ml)

1.2 g vial: Dissolve in 20 ml sterile water for injection B.P. (Final volume 20.9 ml)

A transient pink coloration may appear during reconstitution. Reconstituted solutions are normally a pale, straw colour.

Each 1.2 g Amoclan contains 1mmol potassium and 3.1mmol sodium.

Intravenous injection and infusion:

The stability of Amoclan intravenous solution is concentration dependent, thus Amoclan intravenous should be used immediately after reconstitution and given by slow intravenous injection over a period of 3-4 minutes. Amoclan intravenous solutions should be used within 20 minutes of reconstitution. Intravenous Amoclan may be infused in sterile water for injection B.P. or sodium chloride intravenous injection B.P. (0.9% w/v). Add, without delay, 600 mg reconstituted solution to 50 ml infusion fluid or 1.2 g reconstituted solution to 100 ml infusion fluid (e.g. using a minibag or in-line burette). Infuse over 30-40 minutes and complete within four hours of reconstitution. For other appropriate infusion fluids, see Stability and compatibility section.

* Solutions should be made up to full infusion volume immediately after reconstitution. Any residual antibiotic solutions should be discarded. **Amoclan Intravenous should not be mixed with blood products, other proteinaceous fluids such as protein hydrolysates or with intravenous lipid emulsions.**

If Amoclan is prescribed concurrently with an **aminoglycoside**, the antibiotics should not be mixed in the syringe, intravenous fluid container or giving set because loss of activity of the aminoglycoside can occur under these conditions. Therapy can be started parenterally and continued with oral Amoclan. Treatment should not be extended beyond 14 days without review.

Stability and compatibility

Intravenous infusions of Amoclan may be given in a range of different intravenous fluids. Satisfactory antibiotic concentrations are retained at 5°C and at room temperature (25 °C) in the recommended volume of the following infusion fluids. If reconstituted and maintained at room temperature, infusions should be completed within the times stated.

Intravenous infusion fluids	**Stability period at 25°C**
Water for injection B.P.	4 hours
Sodium chloride intravenous infusion B.P. (0.9% w/v)	4 hours
Sodium lactate intravenous infusion B.P. (one-sixth molar)	4 hours
Compound sodium chloride intravenous infusion B.P. (Ringer's solution)	3 hours
Compound sodium lactate intravenous infusion B.P. (Ringer-lactate solution; Hartmann's solution)	3 hours
Potassium chloride and sodium chloride intravenous infusion B.P.	3 hours

Reconstituted solutions should not be frozen.

Amoclan is less stable in infusions containing glucose, dextran or bicarbonate. Reconstituted solutions of Amoclan should therefore not be added to such infusions but may be injected into the drip tubing over a period of 3-4 minutes. For storage at 5°C, the reconstituted solution should be added to pre-refrigerated infusion bags which can be stored for up to 8 hours. Thereafter, the infusion should be administered immediately after reaching room temperature.

Intravenous infusion fluids	**Stability period at 5°C**
Sterile water for injection B.P.	8 hours
Sodium chloride intravenous infusion B.P. (0.9% w/v)	8 hours

CONTRAINDICATIONS

Hypersensitivity to penicillins.

WARNINGs

Before initiating therapy with any penicillin, careful inquiry should be made concerning previous hypersensitivity reactions or penicillin associated jaundice/ hepatic dysfunction . Attention should be paid to possible cross-sensitivity with other ß-lactam antibiotics, e.g. Cephalosporins.

If any allergic reaction occurs, treatment should be discontinued and the appropriate therapy instituted.

PRECAUTIONS

Amoclan should be used with care in patients with severe hepatic dysfunction. Reversible cholestatic jaundice has been rarely reported. Dosage should be adjusted in patients with moderate or severe renal impairment. With high doses of intravenous Amoclan adequate fluid intake and urinary output should be maintained to minimize the possibility of crystalluria.

Serious and occasionally fatal hypersensitivity (anaphylactoid) reactions have been reported and are more likely to occur in patients with a history of penicillin hypersensitivity.

Erythematous rashes with glandular fever have been associated with amoxycillin

Pregnancy and Lactation: Amoclan is excreted in breast milk (in trace quantities) and may be administered in lactating mothers. Amoclan is FDA category (B). However there are no adequate and well-controlled studies in pregnant women so it should be used during pregnancy only if clearly needed.

Drug Interactions:

Anti-coagulation therapy - prolongation of bleeding time and prothrombin time may occur.

Oral contraceptives - Amoxycillin/clavulanic acid may reduce the efficacy of oral contraceptives.

SIDE EFFECTS

Intravenous Amoclan is generally well tolerated. The majority of side effects observed were of a mild and transient nature. The reported adverse effects include: diarrhoea, indigestion, nausea, vomiting, pseudomembranous colitis, urticarial or erythematous rashes, hepatitis, cholestatic jaundice. Phlebitis at the site of injection has also been reported. As with other ß-lactam antibiotics angioedema, anaphylaxis, transient leucopenia, thrombocytopenia, and hemolytic anemia have been rarely reported.

OVERDOSE

Problems of overdosage with Amoclan are unlikely to occur. Gastrointestinal symptoms and fluid and electrolyte imbalance may be evident. Symptomatic treatment with attention to the water electrolyte balance should be instituted. Amoclan may be removed from the circulation by haemodialysis.

PRESENTATION

Vials

AMOCLAN 1.2 g:	1g Amoxycillin as Amoxycillin sodium and 200 mg Clavulanic acid as potassium clavulanate
AMOCLAN 600 mg:	500 mg Amoxycillin as Amoxycillin sodium and 100 mg Clavulanic acid as potassium clavulanate

THIS IS A MEDICAMENT

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous.
- Follow the doctor's prescription strictly, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of the reach of children

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