

SIZE : 98 X 248 mm
FRONT

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BACK

ASMOCLAV-1.2
(Co-Amoxiclav For Injection BP 1.2G)
PRESCRIBING INFORMATION

Composition:

Each vial contains:
Amoxicillin Sodium BP
Eq. to Amoxicillin 1.0 g
Potassium Clavulanate BP
Eq. to Clavulanic Acid 0.2g

THERAPEUTIC CLASS: Combinations of penicillins, incl. beta-lactamase inhibitors

PHARMACEUTICAL FORM:

Co-Amoxiclav for Injection: White to off white Powder

Diluent (water for injection): Clear colourless to pale yellow solution

DESCRIPTION & PHARMACOLOGICAL ACTION: ASMOCLAV-1.2 is a combination of amoxicillin and clavulanic acid. Amoxicillin destroys bacteria by disrupting their ability to form cell walls. Clavulanic acid blocks the chemical defense, known as beta-lactamase, that some bacteria have against penicillin

Pharmacodynamic properties:

Amoxicillin: 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.

Clavulanic Acid: 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.

Pharmacokinetic properties:

Absorption: The pharmacokinetic results for studies in which amoxicillin/clavulanic acid was administered to groups of healthy volunteers as either 500 mg/100 mg or 1000 mg/200 mg given as a bolus intravenous injection are presented below.

Mean (±SD) pharmacokinetic parameters (<i>t</i>)Bolus intravenous injection						
Dose administered	Dose	Mean peak serum conc (µg/ml)	T _½ (h)	AUC (h.mg/l)	Urinary recovery (% 0 to 6 h)	
	Amoxicillin					
AMX/CA 500 mg/100 mg	500 mg	32.2	1.07	25.5	66.5	
AMX/CA 1000 mg/200 mg	1000 mg	105.4	0.9	76.3	77.4	
	Clavulanic acid					
AMX/CA 500 mg/100 mg	100 mg	10.5	1.12	9.2	46.0	
AMX/CA 1000 mg/200 mg	200 mg	28.5	0.9	27.9	63.8	

Distribution: About 25% of total plasma clavulanic acid and 18% of total plasma amoxicillin is bound to protein. The apparent volume of distribution is around 0.3-0.4 l/kg for amoxicillin and around 0.2 l/kg for clavulanic acid. Following intravenous administration, both amoxicillin and clavulanic acid have been found in gall bladder, abdominal tissue, skin, fat, muscle tissues, synovial and peritoneal fluids, bile and pus. Amoxicillin does not adequately distribute into the cerebrospinal fluid.

Biotransformation: Amoxicillin is partly excreted in the urine as the inactive penicilloic acid in quantities equivalent to up to 10 to 25% of the initial dose. Clavulanic acid is extensively metabolized in man, and eliminated in urine and faeces, and as carbon dioxide in expired air.

Elimination: The major route of elimination for amoxicillin is via the kidney, whereas for clavulanic acid it is by both renal and non-renal mechanisms.

INDICATION:

Asmoclav-1.2 is indicated for the treatment of the following infections in adults and children:

- Severe infections of the ear, nose and throat (such as mastoiditis, peritonsillar infections, epiglottitis, and sinusitis when accompanied by severe systemic signs and symptoms)
- Acute exacerbations of chronic bronchitis (adequately diagnosed)
- 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
- Intra-abdominal infections
- Female genital infections.

Consideration should be given to official guidance on the appropriate use of antibacterial agents.

DOSAGE AND ADMINISTRATION:

Posology

The dose of Asmoclav-1.2 that is selected to treat an individual infection should take into account:

- The expected pathogens and their likely susceptibility to antibacterial agents
- The severity and the site of the infection
- The age, weight and renal function of the patient as shown below.

This Asmoclav-1.2 powder for solution for injection / infusion provides a total daily dose of 3000 mg amoxicillin and 600 mg clavulanic acid when administered as recommended below. If it is considered that a higher daily dose of amoxicillin is required it is recommended that an alternative intravenous formulation of Co-Amoxiclav for injection is selected in order to avoid administration of unnecessarily high daily doses of clavulanic acid.

The duration of therapy should be determined by the response of the patient. Some infections require longer periods of treatment. Treatment should not be extended beyond 14 days without review (regarding prolonged therapy).

Adults and children ≥ 40 kg

For treatment of infections: 1000 mg/ 200 mg every 8 hours.

Children < 40 kg

Recommended doses:

- Children aged 3 months and over: 25 mg/5 mg per kg every 8 hours
- Children aged less than 3 months or weighing less than 4 kg: 25 mg/5 mg per kg every 12 hours.

Elderly: No dose adjustment is considered necessary.

Renal impairment: Dose adjustments are based on the maximum recommended level of amoxicillin.

Hepatic impairment: Dose with caution and monitor hepatic function at regular intervals

Method of administration: Asmoclav-1.2 is for intravenous use. The solution for IV injection is obtained by adding to the vial 20ml of the solvent provided.

Asmoclav-1.2 may be administered either by slow intravenous injection over a period of 3 to 4 min directly into a vein or via a drip tube or by infusion over 30 to 40 min. Asmoclav-1.2 is not suitable for intramuscular administration.

Children aged less than 3 months should be administered Asmoclav-1.2 by infusion only.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION:

Oral anticoagulants: Oral anticoagulants and penicillin antibiotics have been widely used in practice without reports of interaction. However, in the literature there are cases of increased international normalised ratio in patients maintained on acenocoumarol or warfarin and prescribed a course of amoxicillin. If co-administration is necessary, the prothrombin time or international normalised ratio should be carefully monitored with the addition or withdrawal of amoxicillin. Moreover, adjustments in the dose of oral anticoagulants may be necessary.

Methotrexate: Penicillins may reduce the excretion of methotrexate causing a potential increase in toxicity.

Probenecid: Concomitant use of probenecid is not recommended. Probenecid decreases the renal tubular secretion of amoxicillin. Concomitant use of probenecid may result in increased and prolonged blood levels of amoxicillin but not of clavulanic acid.

Mycophenolate mofetil: 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.

CONTRAINDICATIONS:

- Hypersensitivity to the active substances, to any of the penicillins or to any of the excipients.
- History of a severe immediate hypersensitivity reaction to another beta-lactam agent.
- History of jaundice/hepatic impairment due to amoxicillin/clavulanic acid.

SIDE-EFFECTS: Adverse reactions are ranked under heading of frequency, the most frequent first, using the following convention: very common; common; uncommon; rare; very rare; Not known: cannot be estimated from the available data.

The following undesirable effects include those reported with either short-term or long-term use.

Infections and infestations: Common: Mucocutaneous candidosis

Blood and lymphatic system disorders: Rare: Reversible leucopenia (including neutropenia), Thrombocytopenia

Vascular disorders: Rare: Thrombophlebitis

Gastrointestinal disorders: Common: Diarrhoea

Skin and subcutaneous tissue disorders: Rare: Erythema multiforme

WARNINGS AND PRECAUTIONS: Before initiating therapy with amoxicillin/clavulanic acid, careful enquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins or other beta-lactam agents.

Serious and occasionally fatal hypersensitivity reactions (including anaphylactoid and severe cutaneous adverse reactions) have been reported in patients on penicillin therapy. These reactions are more likely to occur in individuals with a history of penicillin hypersensitivity and in atopic individuals. If an allergic reaction occurs, amoxicillin/clavulanic acid therapy must be discontinued and appropriate alternative therapy instituted.

PREGNANCY AND LACTATION:

Pregnancy: Limited data on the use of amoxicillin/clavulanic acid during pregnancy in humans do not indicate an increased risk of congenital malformations. In a single study in women with preterm, premature rupture of the foetal membrane it was reported that prophylactic treatment with amoxicillin/clavulanic acid may be associated with an increased risk of necrotising enterocolitis in neonates.

Breastfeeding: Both substances are excreted into breast milk (nothing is known of the effects of clavulanic acid on the breast-fed infant). Consequently, diarrhoea and fungus infection of the mucous membranes are possible in the breast-fed infant, so that breast-feeding might have to be discontinued.

OVERDOSE:

Symptoms and signs of overdose: Gastrointestinal symptoms and disturbance of the fluid and electrolyte balances may be evident. Amoxicillin crystalluria, in some cases leading to renal failure, has been observed.

Treatment of intoxication: Gastrointestinal symptoms may be treated symptomatically, with attention to the water/electrolyte balance. Amoxicillin/clavulanic acid can be removed from the circulation by haemodialysis.

STORAGE CONDITIONS: Store below 30°C. Protect from light and moisture

Keep the medicine out of reach of children.

After Reconstitution: Chemical and physical in-use stability has been demonstrated for 2-3 hours at 25°C, or 8 hours at 5°C

INCOMPATIBILITIES:

SHELF LIFE: 24 months

PRESENTATION: A white to off white powder filled in 20 ml USP type-I transparent glass vial with 20 ml sterilized water for injection embedded in PVC tray. Such one vial packed in a printed unit carton along with package insert.

CONDITION OF PRESCRIPTION AND DELIVERY: LIST I

DATE OF REVISION OF THE TEXT: 12/2022

MARKETING AUTHORIZATION HOLDER:



Manufactured in India by :

ASMOH LABORATORIES LTD.

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