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

Amoxicillin Capsule I.P.

COMPOSITION:

Each hard gelatin capsule contains :

Amoxycillin Trihydrate	I.P.	
eq. to Amoxycillin		250 mg
Excipients		q.s.

Approved colours used in capsule shell.

AMERICAN
A-MOX 250
ए-मोक्स 250 Capsules

Therapeutic Indications:

This medication is indicated for infections of the throat, nose, and ears, lower respiratory tract infections, genitourinary tract infections without urological complications, infections of the skin and soft tissues, infections in dentistry-stomatology, biliary tract infections, Lyme disease or borreliosis, typhoid and paratyphoid fever, and H.pylori eradication treatment in association with a proton pump inhibitor and, where appropriate, other antibiotics. It is also used for peptic ulcer, low-grade gastric lymphoma of mucosa-associated lymphoid tissue, and endocarditis prophylaxis. Official guidelines regarding bacterial resistance and appropriate antibiotic use must be considered.

Pharmacokinetics and Pharmacodynamics in Humans:

Amoxicillin is a semisynthetic penicillin, sensitive broad-spectrum penicillinase, inhibiting the biosynthesis of the mucopeptide of the bacterial cell wall. Amoxicillin has been reported to be more active in vitro than ampicillin against Enterococcus faecalis and Salmonella spp., but is less active against Shigella spp. It is inactivated by b-lactamases, and cross-resistance between amoxicillin and ampicillin has been reported. The spectrum of activity of amoxicillin may be extended by concomitant use of b-lactamase inhibitors. Amoxicillin is resistant to inactivation by acids in gastric secretions. It is more quickly and completely absorbed when administered orally, with peak plasma concentrations twice as high as a similar dose of ampicillin. The peak plasma concentration of amoxicillin is around 5 mg/ml and has been observed 1 to 2 hours after a 250 mg dose, with detectable amounts present for more than 8 hours. Oral amoxicillin is absorbed up to 98% of the ingested dose. This absorption is little influenced by the ingestion of food. Amoxicillin administered intramuscularly achieves similar concentrations as when administered orally. About 20% is bound to plasma proteins in circulation. The plasma half-life of amoxicillin is 60 minutes. The half-life may be prolonged in neonates and the elderly; In renal failure, the half-life has been 7 to 20 hours. Amoxicillin is widely distributed with varying concentrations in tissues and body fluids, crosses the placenta, and small amounts are excreted in breast milk. Little amoxicillin crosses into the CSF unless the meninges are inflamed. Amoxicillin is metabolized to penicilloic acid, which is excreted in the urine. About 60% of an oral dose of amoxicillin is excreted unchanged in the urine within 6 hours by filtration, glomerular, and tubular secretion. Urinary concentrations above 300 mg/ml have been reported after a 250 mg dose. Probenecid slows renal excretion. Amoxicillin is removed by hemodialysis. High concentrations have been reported in bile, and a small amount can be excreted in feces.

Contraindications:

Amoxicillin should not be administered to patients with a history of hypersensitivity to beta-lactam antibiotics (e.g., penicillins, cephalosporins) or infectious mononucleosis.

Special Warnings and Precautions Employment:

Before starting therapy with amoxicillin, the patient should be investigated for the possible existence of a history of hypersensitivity to penicillins and cephalosporins or an allergic background, primarily of a drug nature. Serious and sometimes fatal hypersensitivity reactions (anaphylaxis) have been observed in patients treated with beta-lactam antibiotics. These reactions usually occur in individuals with a history of hypersensitivity to penicillins. If an allergic reaction occurs, treatment with amoxicillin will be discontinued, and supportive treatment will be instituted. Severe anaphylactic reactions require immediate emergency treatment with adrenaline. Oxygen, intravenous corticosteroids, and maintaining airway patency may also be necessary, including intubation. Prolongation of prothrombin time has rarely occurred in patients treated with amoxicillin. This parameter must be monitored when anticoagulants are prescribed concomitantly. Prolonged use may occasionally result in an increase in non-susceptible microorganisms. Although amoxicillin has low toxicity, it is recommended that organ functions, including kidney function, liver function, and hematopoietic function, be periodically evaluated during prolonged treatments. At high doses, adequate fluid intake and diuresis must be maintained. Doses should be adjusted in patients with renal failure.

Interaction with Other Medicinal Products and Other Forms of Interaction:

It should not be combined with allopurinol as it may increase the possibility of skin rash. It should not be administered together with bacteriostatic antibiotics (chloramphenicol, tetracyclines, erythromycins, or sulfonamides) since these drugs can antagonize their therapeutic action. Probenecid increases serum concentration of amoxicillin, prolongs the elimination half-life, and there is a greater risk of toxicity. However, they can be used simultaneously in the treatment of infections in that high and/or prolonged concentrations of amoxicillin are necessary. Oral amoxicillin may reduce the effectiveness of oral contraceptives.

Incompatibilities:

Should not be associated with bacteriostatic antibiotics (chloramphenicol, tetracyclines) since they antagonize the bacteriostatic action of amoxicillin.

Pregnancy and Breastfeeding:

Amoxicillin can be used during pregnancy when the potential benefits outweigh the risks. There are no known effects on the infant, except for the potential risk of sensitization, due to the presence of traces in maternal milk.

Precautions and Relationship with Effects of Carcinogenesis, Mutagenesis, Teratogenesis, and on Fertility:

Studies in several animal species have shown that amoxicillin lacks carcinogenic effects, mutagenic and teratogenic effects, and does not modify fertility.

Effects on the Ability to Drive and Use Machinery:

There is no evidence of effects on the ability to drive vehicles or use machinery.

Adverse Reactions:

Adverse reactions are rare and generally weak and transient in nature. Gastrointestinal: Phenomena of digestive intolerance

Storage: Store in a cool, dry & dark place. Protect from heat, light & moisture. Temperature not exceeding 30°C.

Keep the medicine out of reach of children.

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