Front

160 mm

120 mm

ACINET

Amoxicillin and Clavulanate potassium

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

Composition

Acinet 1.2g Injection
Each vial contains
Amoxicillin Sodium BP equivalent to Amoxicillin 1 g
Clavulanate potassium USP equivalent Clavulanic acid 200 mg

Acinet 600mg Injection
Each vial contains
Amoxicillin Sodium BP equivalent to Amoxicillin 500 mg
Clavulanate potassium USP equivalent Clavulanic acid 100 mg

Acinet 1000
Each film-coated tablet contains
Amoxicillin Trihydrate USP equivalent to Amoxicillin 875 mg
Clavulanate potassium USP equivalent Clavulanic acid 125 mg
Colour: Titanium Dioxide USP

Acinet 625
Each film-coated tablet contains
Amoxicillin Trihydrate USP equivalent to Amoxicillin 500 mg
Clavulanate potassium USP equivalent Clavulanic acid 125 mg
Colour: Titanium Dioxide USP

Acinet 375
Each film-coated tablet contains
Amoxicillin Trihydrate USP equivalent to Amoxicillin 250 mg
Clavulanate potassium USP equivalent Clavulanic acid 125 mg
Colour: Titanium Dioxide USP

Acinet Dry Syrup 156,25mg/5ml
Each 5ml of the reconstituted suspension contains:
Amoxicillin Trihydrate USP equivalent to Amoxicillin 125 mg
Clavulanate Potassium USP equivalent to Clavulanic acid 31,25 mg

Acinet Dry Syrup 228.5mg/5ml
Each 5ml of the reconstituted suspension contains:
Amoxicillin Trihydrate USP equivalent to Amoxicillin 200 mg
Clavulanate Potassium USP equivalent to Clavulanic acid 28.5 mg

Acinet Dry Syrup 312.5mg/5ml
Each 5ml of the reconstituted suspension contains:
Amoxicillin Trihydrate USP equivalent to Amoxicillin 250 mg
Clavulanate Potassium USP equivalent to Clavulanic acid 62.5 mg

Acinet Dry Syrup 457mg/5ml
Each 5ml of the reconstituted suspension contains:
Amoxicillin Trihydrate USP equivalent to Amoxicillin 400 mg
Clavulanate Potassium USP equivalent to Clavulanic acid 57 mg

Clinical Pharmacology

Pharmacodynamics

Acinet is a formulation of amoxicillin and clavulanic acid. Amoxicillin has a broad spectrum of bactericidal activity against many gram-positive and gram-negative microorganisms. Amoxicillin is, however, susceptible to degradation by (beta)-lactamases, and therefore, the spectrum of activity does not include organisms which produce these enzymes. The formulation of amoxicillin and clavulanic acid in Acinet protects amoxicillin from degradation by (beta)-lactamase enzymes and effectively extends the antibiotic spectrum of amoxicillin to include many bacteria normally resistant to amoxicillin and other (beta)-lactam antibiotics.

Amoxicillin/clavulanic acid has been shown to be active against most strains of the following microorganisms, both in vitro and in clinical infections.

Gram-Positive Microorganisms:

Aerobes
Staphylococcus aureus
Coagulase-negative Staphylococci (Including Staphylococci epidermidis)
Streptococcus pyogenes
Bacillus anthracis
Corynebacterium species
Streptococcus viridans
Enterococcus faecium
Enterococcus faecalis
Listeria monocytogenes
Streptococcus agalactiae
Anaerobes:
Clostridium species
Peptococcus species
Peptostreptococcus species

Gram-Negative Microorganisms:

Aerobes
Escherichia coli
Proteus mirabilis
Proteus vulgaris
Klebsiella species
Salmonella species
Shigella species
Bordetella pertussis
Gardnerella vaginalis
Legionella species
Brucella species
Neisseria meningitidis
Neisseria gonorrhoeae
Haemophilus influenzae
Moraxella catarrhalis
Pasteurella multocida
Vibrio cholerae
Helicobacter pylori
Yersinia enterocolitica
Anaerobes
Bacteroides species including B. fragilis
Fusobacterium species

Pharmacokinetics

Combining clavulanic acid with amoxicillin causes no appreciable alteration of the pharmacokinetics of either drug compared with their separate administration. After oral administration, both components achieve maximum plasma concentration in about an hour. Absorption is unaffected by food, milk, ranitidine or pirenzepine. The tissue and body fluid distribution of both components is generally adequate to achieve antibacterial levels, although the concentrations may be somewhat low in bronchial secretions and cerebrospinal fluid. The pharmacokinetic profile of amoxicillin and clavulanic acid in children parallels that in adults.

Indications

Acinet is indicated in the treatment of infections caused by susceptible strains of the designated organisms in the conditions listed below:

Lower Respiratory Tract Infections - caused by (beta)-lactamase producing strains of H. influenzae and M. catarrhalis

Otitis Media - caused by (beta)-lactamase producing strains of H. influenzae and M. catarrhalis.

Sinusitis - caused by (beta)-lactamase producing strains of H. influenzae and M. catarrhalis.

Skin and Skin Structure Infections - caused by (beta)-lactamase producing strains of S. aureus, E. coli and Klebsiella spp.

Urinary Tract Infections - caused by (beta)-lactamase producing strains of E. coli, Klebsiella spp. and Enterobacter spp.

Bone and Joint Infections

Other infections e.g. intra-abdominal sepsis and dental infections

While Acinet is indicated only for the conditions listed above, infections caused by ampicillin-susceptible organisms are also amenable to treatment with Acinet due to its amoxicillin content. Therefore, mixed infections caused by ampicillin-susceptible organisms and (beta)-lactamase producing organisms susceptible to Acinet should not require the addition of another antibiotic. Because amoxicillin has greater in vitro activity against S. pneumoniae than does ampicillin or penicillin, the majority of S. pneumoniae strains with intermediate susceptibility to ampicillin or penicillin are fully susceptible to amoxicillin and Acinet.

Dosage and Method of Administration

Acinet Injection

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

Usual dosages for the treatment of infection:

Back

160 mm

120 mm

Adults and children over 12 years:

Usually 1.2 g thrice daily. In more serious infections, increase frequency to 6 hourly intervals. Maximum adult daily dose should not exceed 7.2 g IV route.

Children 3 months - 12 years Usually 30 mg/kg Acinet 8 hourly.In more serious infections, increase frequency to 6 hourly

* Each 30 mg of Acinet I.V. provides 5 mg clavulanic acid and 25 mg amoxicillin. Therapy can be started parenterally and continued with the oral preparation. Treatment with Acinet should not extend beyond 14 days without review.

Dosage for Surgical Prophylaxis

Procedures lasting for less than 1 hour are covered in adults by 1.2 g Acinet I.V. given at induction of anaesthesia. Longer operation require subsequent doses of 1.2 g Acinet I.V. (up to 4 doses in 24 hours), and this regimen can be continued for several days if the procedure has significantly increased risk of infection. Clear clinical signs of infection at operation will require a normal course of intravenous or oral Acinet therapy post-operatively.

Renal Impairment

Adults

Mild impairment: No change in dosage

Moderate impairment: 1.2 g I.V stat followed by 600 mg I.V q 12 hourly

Severe impairment: 1.2 g I. V stat followed by 600 mg I.V q 12 hourly. An additional 600 mg IV dose may need to be given during dialysis and at the end of dialysis.

Children

Similar reductions in dosage should be made for children.

Hepatic Impairment

Dose with caution; monitor hepatic function at regular intervals.

Acinet Tablets

Adults and Children over 12 years.

Mild to Moderate Infections: One 625 mg tablet twice a day.

Dentoalveolar abscess: one Acinet 625 mg tablet twice a day for five days.

Acinet Dry Syrup

Usual dosages for the treatment of infection:

Patients aged 12 weeks (3 months) and older.

Mild to Moderate infections: 25/3,6 mg/kg/day b.i.d

Severe Infections and Otitis media, sinusitis, lower respiratory infections:

45/6,4 mg/kg/day b.i.d

Contraindications

Acinet is contraindicated in patients with a history of allergic reactions to any penicillin. Attention should be paid to possible cross-sensitivity with other beta-lactam antibiotics, e.g. cephalosporins. It is also contraindicated in patients with a previous history of cholestatic jaundice/hepatic dysfunction associated with amoxicillin-clavulanate.

Warnings and Precautions

Before initiating therapy with Acinet, careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins, or other allergens. If an allergic reaction occurs, Acinet should be discontinued and the appropriate therapy instituted. Pseudomembranous colitis has been reported with nearly all antibacterial agents, including Acinet, and has ranged in severity from mild to life-threatening. Mild cases of Pseudomembranous colitis usually respond to drug discontinuation alone. In moderate to severe cases, consideration should be given to management with fluids and electrolytes, protein supplementation, and treatment with an antibacterial drug clinically effective against C. difficile colitis.

If the parenteral administration of high doses is necessary, the sodium content must be taken into account in patients on a sodium restricted diet.

Change in liver function tests have been observed in some patients receiving amoxicillin- clavulanate. The clinical significance of these changes is uncertain but Acinet should be used with caution in patients with evidence of severe hepatic dysfunction. Cholestatic jaundice, which may be severe, but is usually reversible, has been reported rarely. Signs and symptoms may not become apparent for several weeks after treatment has ceased.

Acinet should be avoided if infectious mononucleosis is suspected since the occurrence of morbilliform rash has been associated with this condition following the use of amoxicillin. In patients with moderate or severe renal impairment Acinet Dry Syrup 228 mg/5 ml is not recommended. Erythematous rashes have been associated with glandular fever in patients receiving amoxicillin. Acinet should be avoided if glandular fever is suspected. Prolonged use may also occasionally result in overgrowth of non-susceptible organisms. In patients with reduced urine output, crystalluria has been observed very rarely, predominantly with parenteral therapy. During the administration of high doses of amoxicillin, it is advisable to maintain adequate fluid intake and urinary output in order to reduce the possibility of amoxicillin crystalluria.

Acinet Dry Syrup 228 mg/5mL contains 12.5mg aspartame per 5mL dose and therefore care should be taken in phenylketonuria.

While Acinet possesses the characteristic low toxicity of the penicillin group of antibiotics, periodic assessment of organ system functions, including renal, hepatic, and hematopoietic function, is advisable during prolonged therapy.

Drug Interactions

Probenecid: Probenecid decreases the renal tubular secretion of amoxicillin. Concurrent use with Acinet may result in increased and prolonged blood levels of amoxicillin. Co-administration of probenecid cannot be recommended.

Anticoagulants: Prolongation of bleeding time and prothrombin time have been reported in some patients receiving amoxicillin/clavulanic acid, Acinet should be used with care in patients on anti-coagulation therapy.

Allopurinol : The concurrent administration of allopurinol and amoxicillin increases substantially the incidence of rashes in patients receiving both drugs as compared to patients receiving amoxicillin alone. There are no data with Acinet and allopurinol administered concurrently.

Contraceptives: In common with other broad-spectrum antibiotics, Acinet may reduce the efficacy of oral contraceptives.

Renal Impairment: Please refer dosage and administration.

Hepatic Impairment: Please refer dosage and administration.

Pregnancy (Category B): There are no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy only if clearly needed.

Lactation: Acinet may be administered during lactation. With the exception of the risk of sensitization, associated with the excretion of trace quantities in breast milk, there are no known detrimental effects for the infant.

Paediatrics: As per directions given in dosage and administration.

Undesirable Effects

Amoxicillin- clavulanate is generally well tolerated. The majority of side effects observed in clinical trials were of a mild and transient nature and less than 3% of patients discontinued therapy because of drug-related side effects. From the original premarketing studies, where both paediatric and adult patients were enrolled, the most frequently reported adverse effects were diarrhoea/loose stools (9%), nausea (3%), skin rashes and urticaria (3%), vomiting (1%) and vaginitis (1%). The overall incidence of side effects, and in particular diarrhoea, increased with the higher recommended dose. Other less frequently reported reactions include: Abdominal discomfort, flatulence, and headache.

Overdosage

Following overdosage, patients have experienced primarily gastrointestinal symptoms including stomach and abdominal pain, vomiting, and diarrhoea. Rash, hyperactivity, or drowsiness has also been observed in a small number of patients.

In the case of overdosage, discontinue Acinet, treat symptomatically, and institute supportive measures as required. If the overdosage is very recent and there is no contraindication, an attempt at emesis or other means of removal of drug from the stomach may be performed.

Interstitial nephritis resulting in oliguric renal failure has been reported in a small number of patients after overdosage with amoxicillin. Crystalluria, in some cases leading to renal failure, has also been reported after amoxicillin overdosage in adults and pediatric patients. In case of overdosage, adequate fluid intake and diuresis should be maintained to reduce the risk of amoxicillin crystalluria.

Renal impairment appears to be reversible with cessation of drug administration. High blood levels may occur more readily in patients with impaired renal function because of decreased renal clearance of both amoxicillin and clavulanate. Both amoxicillin and clavulanate are removed from the circulation by hemodialysis.

Incompatibilities

Acinet intravenous should not be mixed with blood products, other proteinaceous fluid such as protein hydrolysates or with intravenous lipid emulsions. If Acinet 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.

Storage: Store at a temperature not exceeding 30°C.

Protected from light and moisture.

Keep out of reach of children.

Presentation:

ACINET 375, 625, 1000, Alu Alu Blister of 10 tablets

ACINET Dry syrup 156,25mg/5ml, 228,5mg/5ml, 312,5mg/5ml, 457mg/5ml

30ml, 60ml, 70ml, 100ml amber glass bottle.

ACINET 600 mg & 1.2G Clear colourless glass vial.

PI0189

Manufactured by:
INDCHEMIE HEALTH SPECIALITIES PVT. LTD.
Village-Thana, Tehsil-Baddi, Dist-Solan,
Himachal Pradesh-173 205. India.

Marketed by:
CACHET PHARMACEUTICALS PVT. LTD.
415, Shah Nahar, Worli, Mumbai 400 018. INDIA.
www.cachetindia.com