AMPICLO-DAWA

(AMPICILLIN/CLOXACILLIN DROPS/POWDER FOR SUSPENSION/CAPSULES/INJECTION)

Composition

Each 0.6 ml suspension of the drops contains 60mg Ampicillin (as trihydrate) BP and 30mg cloxacillin (as sodium) BP.
Each vial contains 250mg Ampicillin (as trihydrate) BP and 250mg Cloxacillin (as sodium) BP.
Each capsule contains 250mg Ampicillin (as trihydrate) BP and 250mg Cloxacillin (as sodium) BP.
Each 5ml of the reconstituted dry powder for oral suspension contains 125mg Ampicillin (as trihydrate) BP and 125mg Cloxacillin (as sodium) BP.
Each 5ml of the reconstituted dry powder for oral suspension contains 62.5mg Ampicillin (as trihydrate) BP and 62.5mg Cloxacillin (as sodium) BP.

Pharmacology

Ampicillin exerts its bactericidal action on growing and dividing bacteria by inhibiting bacterial cell-wall synthesis. Ampicillin inhibits the final cross-linking stage of peptidoglycan production by binding to and inactivating trans-peptidases, penicillin-binding proteins on the inner surface of the bacterial cell membrane.
Cloxacillin is a narrow spectrum antibiotic and is not inactivated by staphylococcal beta-lactamases.
Cloxacillin, by its action on the synthesis of the bacterial wall, exerts a bactericidal effect on streptococci, staphylococci, including the beta-lactamase-producing strains, clostridia and neisseria. It is not active against methicillin-resistant staphylococci.

Pharmacokinetics

Ampicillin is relatively resistant to inactivation by gastric acid and is moderately well absorbed from the gastrointestinal tract after oral doses. Peak concentrations in plasma are attained in about 1 to 2 hours and after a 500-mg oral dose are reported to range from 3 to 6 micrograms/ml. Ampicillin is widely distributed and therapeutic concentrations can be achieved in ascitic, pleural, and joint fluids. It crosses the placenta and small amounts are distributed into breast milk.
Cloxacillin is incompletely absorbed from the gastrointestinal tract, and absorption is reduced by the presence of food in the stomach. About 94% of cloxacillin in the circulation is bound to plasma proteins.
Cloxacillin has been reported to have a plasma half-life of 0.5 to 1 hour. The half-life is prolonged in neonates.
Cloxacillin crosses the placenta and is distributed into breast milk. Cloxacillin is metabolised to a limited extent, and the unchanged drug and metabolites are excreted in the urine by glomerular filtration and renal tubular secretion.

Indications

Respiratory tract infections, urinary tract infections, skin and soft tissue infections, septicemia, orthopedic infections, ear, nose and throat infections, gastrointestinal infections, pelvic infections and endocarditis.
The neonatal drops are indicated for the prophylaxis or treatment of bacterial infections in premature babies or neonates, such as following amniotic fluid infection or delayed or complicated delivery.

Dosage and directions for use

Adults and children over 10years: 500mg –1g every 6 hours.
Children 3 –10 years: 250 –500mg every 6 hours.
Children 1- 2 years: 250mg every 6 hours.
Neonates: 90mg (0.6 ml i.e. to mark on pipette) every 4 hours.
Note: Best results are obtained if dosages are administered half to one hour prior to meals or at least two hours after meals

Adverse reactions, contraindications and precautions

Ampiclo-Dawa may produce diarrhea, nausea and heartburn. Allergic reactions which may include exfoliative dermatitis, other skin rashes, interstitial nephritis and vasculitis may occur. A generalised sensitivity reaction with urticaria, fever, joint pains and eosinophilia can develop within a few hours to several weeks after starting treatment.
Superinfections by resistant species, such as Pseudomonas or Candida, which do not respond to penicillin therapy, may occur.

Drug Interactions

Ampiclo-Dawa may decrease the efficacy of oestrogen-containing oral contraceptives.
Probenecid inhibits renal tubular secretion of ampicillin, avoid use together. High doses of penicillin may interfere with renal tubular secretion.

Pregnancy and lactation

Use with caution

Presentation

Drops: Amber Bottles containing powder for reconstitution of 8ml of suspension with a calibrated dropper provided.
Dry powder for suspension: Bottles containing powder for reconstitution of 60ml and 100ml of suspension.
Capsules: 500 capsules in plastic jars, 10 x 10 capsule blisters in unit carton packs.
10 vial per unit pack

Distribution Category:

POM

Storage

Store in a cool dry place below 30°C. Protected from direct sunlight.
Dry powder for suspension: Once reconstituted, store the bottle tightly closed in a cool dry place, below 30°C, preferably in a refrigerator. Do not freeze. To be used within 7 days after reconstitution.
Keep all medicines out of reach of children.

Manufactured in Kenya by:

DAWA Limited, Plot No. 7879/8, Baba Dogo Road, Ruaraka
P. O. Box 16633 – 00620, Nairobi, Kenya.

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