MOXAFORTE ®

Flucloxacillin BP 250mg and Amoxicillin BP 250mg and capsules

Qualitative and quantitative composition

Each capsule contains: Amoxicillin (as Trihydrate) BP 250mg
and Flucloxacillin (as Sodium) BP 250mg.

Excipients

Magnesium stearate, Microcrystalline cellulose pH 102 and
Hard Gelatin capsules size '0'.

Pharmaceutical form:

Powder for oral suspension
A whitish coloured, free flowing granular powder yields a yellow coloured suspension on reconstitution.

Pharmacology

J01RA01 –Penicillins, combination with other antibacterial
Amoxicillin is bactericidal Like all penicillins it acts by interfering with the synthesis of the cell wall of the bacterium. Amoxicillin is inactivated by penicillinase.
Flucloxacillin is antibiotic of the group of isoxazolyl penicillins, The bactericidal activity results from the inhibition of cell wall synthesis and is mediated through Flucloxacillin binding to penicillin binding proteins (PBPs). Flucloxacillin is stable against hydrolysis by a variety of beta-lactamases, including penicillinases and cephalosporinases and extended spectrum beta-lactamases.
a)Bacteriology: The two components amoxycillin and flucloxacillin exhibits in vitro and in experimental animals in vivo, bactericidal activity against a wide range of Gram-positive and Gram-negative bacteria. The following are among the more commonly encountered sensitive organisms: Gram-positive bacteria, Gram-negative bacteria, Streptococcus pyogenes, Neisseria gonorrhoeae, Strep. Faecalis, Neisseria meningitides, Strep. Viridans, Haemophilusinfluenzae, Dip. Pneumoniae, Iscerichia coli, Staphylococcus aureus,Salmonella typhi, (penicillin sensitive) Salmonella species, Staphylococcus aureus, Proteus mirabilis, (penicillinase producing), Bordetella pertussis, Corynebacterium species, Shigella species, Clostridium species, Brucella species, Bacillus anthracis,
Synergism: Moxaforte exhibits synergistic bactericidal activity in vitro, and in experimental animals in vivo against some ampicillin-resistant organisms.
Additive effects: The two components amoxycillin and flucloxacillin – generally exhibit an additive effect against sensitive bacteria and bacteria that are sensitive to amoxycillin or to flucloxacillin remain sensitive to the combination, showing that antagonism does not occur when the two components are combined.

Pharmacokinetics:

oral administration. The presence of food does not interfere with this process. Peak plasma concentrations are obtained in about 1-2 hours, Protein binding is about to 20%.Effective levels in the cerebrospinal fluid are obtained only in the presence of inflammation and then irregularly. About 60% of an orally administered dose is excreted unchanged in the urine. It penetrates well in to purulent and mucoid sputum. In preterm infants with gestational age 26-33 weeks, the total body clearance after intravenous dosing of amoxicillin, day 3 of life, ranged between 0.75 – 2 ml/min, very similar to the insulin clearance (GFR) in this population. Following oral administration, the absorption pattern and the bioavailability of amoxicillin in small children may be different to that of adults. Consequently, due to the decreased CL, the exposure is expected to be elevated in this group of patients, although this increase in exposure may in part be diminished by decreased bioavailability when given orally.
Flucloxacillin is stable in acid media and can therefore be administered either by the oral or parenteral route. The peak serum levels of Flucloxacillin reached after one hour are as follows. - After 250mg by the oral route (in fasting subjects): Approximately 8.8mg/l

- After 500mg by the oral route (in fasting subjects): Approximately 14.5mg/l
- After 500mg by the IM route: Approximately 16.5mg/l

The total quantity absorbed by the oral route represents approximately 79% of the quantity administered. Flucloxacillin diffuses well into most tissue. Specifically, active concentrations of Flucloxacillin have been recovered in bones: 11.6mg/1 (compact bone) and 15.6mg/l (spongy bone), with a mean serum level of 8.9mg/l. Flucloxacillin diffuses in only small proportion into the cerebrospinal fluid of subjects whose meninges are not inflamed. Crossing into mothers' milk: Flucloxacillin is excreted in small quantities in mothers' milk.
In normal subjects approximately 10% of the Flucloxacillin administered is metabolized to penicilloic acid. The elimination half-life of Flucloxacillin is in the order of 53 minutes. Excretion occurs mainly through the kidney. Between 65.5% (oral route) and 76.1% (parenteral route) of the dose administered is recovered in unaltered active form in the urine within 8 hours. A small portion of the dose administered is excreted in the bile. The excretion of Flucloxacillin is slowed in cases of renal failure.
Protein binding: The serum protein-binding rate is 95%.

Therapeutic indications

Moxaforte is indicated for the treatment of a wide range of bacterial infections, caused by susceptible organisms; in particular infections of mixed origin where penicillin-resistant staphylococci may be implicated or where the causative organism is unknown.
Typical indications include: Acute and chronic bronchitis, Pelvic inflammatory disease, Pneumonia, Urinary tract infections, Ear, nose and throat infections, Skin and soft tissue infections and Gynaecological infections

Posology and method of administration

For oral administration.
Dosage and direction for use.
Children 2-12 years: 5ml of the suspension three times a day.
Children under 2 years: 2.5ml of suspension three times a day.
In severe infections, these dosages may safely be increase
To ensure maximal absorption, Moxaforte should be given in the fasting state, i.e. approximately 1 hour before meal.

Contraindications

Moxaforte should not be given to those subjects hypersensitive to penicillin or Cephalosporins.
Attention should be pay to possible cross-sensitivity with other beta lactam antibiotics e.g Cephalosporin.
Not recommended to neonates.

Interaction with other medicinal products

Probenecid prolongs the half-life of Flucloxacillin and Amoxicillin by competing with them for renal tubular secretion. Flucloxacillin and Amoxicillin may also interact with bacteriostatic antibacterial such as Chloramphenicol and tetracyclines and may be incompatible in vitro with other drugs, including a number of other antibacterials.
Concomitant administration of amoxycillin and anticoagulants from the coumarin class may prolong the bleeding time. A dose adjustment of anticoagulants may be necessary

Pregnancy and lactation

Moxaforte should be used only during pregnancy or lactation when the potential benefits outweigh the potential risks associated with treatment.
Breastfeeding: Moxaforte should be avoided because it is passed through breast milk
Only use during lactation when the potential benefits outweigh the potential risks

Effects on ability to drive and use machines

No effect on driving and use of machines.

Undesirable effects

As with other penicillins, side-effects are rare and usually of a mild and transitory nature. Allergic reactions may occur, and these are normally mild in nature, presenting as a pruritic skin rash, an erythematous skin reaction or urticaria. In this event withdrawal and administration of an antihistamine will suffice in most cases. Should a serious anaphylactic reaction occur the drug should be discontinued and the patient treated with the usual agents: (adrenaline, corticosteroids and antihistamines).
Moxaforte may give rise to a maculopapular rash during therapy or within a few days after completion thereof.
The incidence of maculopapular rash is especially high in patients suffering from infectious mononucleosis.
Hepatitis and cholestatic jaundice have been reported rarely.

Overdose

No known symptoms of overdosage.
As with all penicillins, oral administration can cause gastro-intestinal symptoms such as transient diarrhoea, nausea and colic which are dose related.

Shelf life

3 years from the date of manufacture

Special precautions for storage

Store in a dry place, below 30°C, protected from light.
Keep all medicines out of reach of children

Nature and contents of container

Blister pack of 2 x 10's in a unit box along with a literature insert.

Marketing authorization holder

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

Legal category: Prescription only medicine, (POM).

Manufactured by:

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

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