MOXAFORTE
DRY POWDER, CAPSULES

Composition:
Each 5ml of the reconstituted suspension contains amoxicillin (as trihydrate) 125 mg and flucloxacillin (as sodium) 125 mg.
Each capsule contains amoxicillin (as trihydrate) 250 mg and flucloxacillin (as sodium) 250 mg.
List of excipients:
Capsules: Magnesium stearate and blue/yellow empty shells size `O'.
Dry Powder: Disodium Edetate, Sodium Benzoate, Sodium Citrate anhydrous, Sodium CMC, Sodium Chloride, Tartrazine yellow color, Strawberry powder Flavor and Sucrose.
Pharmacology:
Flucloxacillin is a narrow spectrum antibiotic of the group of isoxazolylpenicillins; it is not inactivated by staphylococcal beta-lactamases. Amoxicillin is the 4-hydroxy analogue of ampicillin. Flucloxacillin's resistance to beta lactamase inhibition makes the combination of Amoxicillin and flucloxacillin active against both beta lactamase and non-beta lactamase producing staphylococci. The structure of the penicillins related to that of intermediates known to be involved in the synthesis of cell wall material. Penicillins interfere with a transpeptidation reaction responsible for the cross-linking of mucopeptide chains in the cell wall polymer of the bacteria. The ability of the penicillins to interfere with this reaction is attributed to its putative structural resemblance to the D-alanyl-D-alanine portion of the peptide chain.
Bacteriology
(i) Spectrum
MoxaForte 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
Streptococcus pyogenes, Strep.faecalis, Strep. Viridans, Dip. Pneumoniae, Staphylococcus aureus (Penicillin sensitive), Staphylococcus aureus, (penicillinase producing), Corynebacterium species.
Clostridium species, Bacillus anthracis.
Gram-negative bacteria
Neisseria gonorrhoeae, Neisseria meningitidis, Haemophilusinfluenzae, Escherichia coli, Salmonella typhi, Salmonella species, Proteus mirabilis, Bordetella pertussis, Shigella species, Brucella species
(ii) Synergism
MoxaForte exhibits synergistic bactericidal activity in vitro, and in experimental animals in vivo against some ampicillin-resistant organisms.
(iii) Additive effects
The two components of MoxaForte –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:
MoxaForte is well absorbed orally. Peak serum levels are achieved 1 to 2 hours after dosing.
Approximately 50% of the dose is excreted unchanged into the urine within 6 hours, resulting in high urine levels of active drug.
Indications:
Moxaforteis 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, Pneumonia, Ear, nose and throat infections, Gynecological infections, Pelvic inflammatory disease, Urinary tract infections, Skin and soft tissue infections.
Contra-indications:
Moxaforte should not be given to those subjects hypersensitive to penicillin.Attention should be paid to possible cross-sensitivity with other beta-lactam antibiotics e.g Cephalosporins.
Dosage and directions for use:
Adults and children above 12yrs: One capsule three times a day.
Children 2–12yrs: 5ml of suspension three times a day.
Children under 2yrs: 2.5ml of suspension three times a day.
In severe infections these dosages may safely be increased.
To ensure maximal absorption Moxaforte should be given in the fasting state, i.e. approximately 1 hour before a meal.
Use in pregnancy and lactation
Pregnancy: This medication is considered safe. However, still medical advice must be sought before use.
Breastfeeding: Moxaforte capsules should be avoided because it is passed through breast milk and may affect the baby.
Side-effects and special precautions:
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 of MoxaForte 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).
Treatment with 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.
Caution: The product contains **Tartrazine Yellow Colour** which can cause potential lethal asthma attacks and nettle rash, hives, DNA damage, tumors of the thyroid and ADHD (Attention Deficit Hyperactivity Disorder). Other side effects of Tartrazine yellow colour are anxiety attacks, itching, rhinitis, urticaria, general weakness, fever, migraine, clinical depression, blurred vision, palpitations, feeling of suffocation, pruritus, purple skin patches and sleep disturbance. In rare cases, Tartrazine side effects are noticeable even at minute doses and can last up to 72 hours after exposure.
Interactions:
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.
Overdosage and treatment
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.
Packaging:
Capsules: Blister pack of 2 x 10's in a unit box.
Oral suspension: Dry powder for reconstitution in 100ml bottles
Storage instructions:
Store in a cool dry place, below 30°C, protected from direct sunlight.
Dry powder for suspension:
Once reconstituted, preferably store in a refrigerator and use within 7 days.
Manufactured by:

DAWA Limited, Plot No. 7879/8, Baba Dogo Road, Ruaraka
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