SUMMARY OF PRODUCT CHARACTERISTICS.

1.0 Name of the medicinal product

Moxaforte 500 Capsules.

2.0 Qualitative and quantitative composition

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

For more information on excipients see section 6.1

3.0 Pharmaceutical form: Capsule for oral administration.

White powder filled in a cylindrical hard gelatin capsule of a yellow body printed "MOXAFORTE" in black colour and a blue cap printed Dawa logo in white colour.

4.0 Clinical particulars

4.1 Therapeutic indications

Moxaforte® offers broad spectrum antibiotic therapy across a wide range of infections including:

- Pelvic infections
- Respiratory tract infections
- Skin and soft tissue infections
- Upper respiratory tract infection
- Urinary tract infections.

4.2 Posology and method of administration:

Method of administration: For oral administration.

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.

4.3 Contraindications

Moxaforte should not be given to those subjects hypersensitive to penicillin.

Attention should be pay to possible cross-sensitivity with other beta lactam antibiotics e.g. Cephalosporin.

4.4 Special warnings and precautions for use

Before initiating therapy with any penicillin, careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins, or other beta-lactam agents. Convulsions may occur in patients with impaired renal function or in those receiving high doses or in patients with predisposing factors (e.g. history of seizures, treated epilepsy or meningeal disorders. In patients with renal impairment the dose should be adjusted accordingly to the degree of impairment. Prolongation of prothrombin time has been reported rarely in patients receiving amoxicillin. Elevated serum and urinary levels of amoxicillin are likely to affect certain laboratory tests. Due to the high urinary concentrations of amoxicillin, false positive readings are common with chemical methods.

4.5 Interaction with other medicinal products and other forms of interaction

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.

4.6. Pregnancy and lactation

Breastfeeding: There is no evidence that Amoxicillin is teratogenic or foetotoxic in humans. The product has been in extensive clinical use for many years and is considered safe in pregnancy.

Flucloxacillin should only be used in pregnancy when the potential benefits outweigh the potential risks associated with treatment.

Lactation: Trace quantities of Flucloxacillin can be detected in breast milk. The possibility of hypersensitivity reactions must be considered in breast-feeding infants. Therefore Flucloxacillin should only be administered to a breast-feeding mother when the potential benefits outweigh the potential risks associated with the treatment.

Amoxicillin is considered safe in lactation. However it should be noted that amoxicillin is excreted in breast milk in small quantities with the possible risk of sensitization and subsequent allergic reactions in a sensitized infant.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed. However, undesirable effects may occur (e.g. allergic reactions, dizziness, convulsions), which may influence the ability to drive and use machines.

4.8 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). Treatment with Flucloxacillin and Moxaforte combinations 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.

4.9 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.

5. 0 Pharmacological properties

5.1 Pharmacodynamic properties.

Pharmacotherapeutic group: ***Penicillins, combination with other antibacterials; ATC code: J01RA01.***

Pharmacology:

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. Penicillinase-producing strains of Staphylococcus aureus and Gram negative organisms (e.g. Escherichia coli, Proteus, Klebsiella) are resistant.

Flucloxacillin is a penicillin beta-lactam antibiotic used in the treatment of bacterial infections caused by susceptible, usually gram-positive, organisms. The name "penicillin" can either refer to several variants of penicillin available, or to the group of antibiotics derived from the penicillins. Flucloxacillin has *in vitro* activity against gram-positive and gram-negative aerobic and anaerobic bacteria. The bactericidal activity of Flucloxacillin 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.

5.2 Pharmacokinetic properties

Amoxicillin is stable in the acid gastric secretion and is rapidly absorbed from the gastrointestinal tract after oral administration. The presence of food does not interfere with this process. Peak plasma concentrations are obtained in about two hours, producing around 2.5 times the peak concentration resulting from comparable doses of ampicillin. Protein binding is similar to that of ampicillin: up to 25%.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 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: l1.6mg/1 (compact bone) and l5.6mg/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.

5.3 Preclinical safety data

Not applicable.

6. Pharmaceutical particulars

6.1 List of excipients

Magnesium stearate,
Microcrystalline cellulose pH 102
Hard Gelatin capsules size ‘0’.

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months from the date of manufacture. (3 years)

6.4 Special precautions for storage

Store in a dry place, below 30°C. Protect from direct sunlight.
Keep all medicine out of children reach.

6.5 Nature and contents of container

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

6.6 Special precautions for disposal and other handling

None applicable.

7.0 Marketing authorization holder/Registrant.

Dawa Limited

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P.O Box 16633-00620, Nairobi –Kenya

7.1 Local Technical Representative in Rwanda.

Sun Enterprises

P.O. Box 933 Kigali.

Rwanda

8. Marketing authorization number(s)

H2011/19994/453

9. Date of first authorization: 1st Dec 2011

Renewal of the authorization: Annually.

10. Date of revision of the text: November 2017