Summary product characteristics:

1. Name of the medicinal product

Dawaclox 250mg capsules

2. Qualitative and quantitative composition

Each capsule contains: Cloxacillin (as sodium) BP 250mg

For the full list of excipients, see section 6.1

3. Pharmaceutical form: Capsule

White powder filled in a cylindrical hard gelatin capsule of an Orange body printed "DAWACLOX 250" in black colour and a black cap printed Dawa logo in white colour..

4. Clinical particulars

4.1 Therapeutic indications

Cloxacillin Sodium is used for the treatment of infections due to staphylococci resistant to benzylpenicillin.

It is also used for mixed streptococcal and staphylococcal, infections when the staphylococci are penicillin-resistant.

Typical indications include: skin and soft tissue infections (boils, abscesses, carbuncles, furunculosis, cellulitis, infected wounds, infected burns, protection for skin grafts, otitis media and externa), respiratory tract infections (pneumonia, lung abscess, empyema, sinusitis, pharyngitis, tonsillitis, quinsy).

Other infections include: osteomyelitis, enteritis, endocarditis, urinary tract infections, meningitis and septicaemia.

4.2 Posology and method of administration

Route of administration: Oral administration.

Adults and children over 12 years of age : The recommended dosage of Ibuprofen is 1200-1800 mg daily in For oral administration only

Capsules: Adults: One 500 mg capsule six hourly, administered one hour before meals.

Children: 2-10 yrs One 250 mg capsule six hourly, administered one hour before meals

4.3 Contraindications.

Use with caution in patients with a known history of allergy to penicillin’s.

When administered to a patient with penicillin sensitivity anaphylactic shock may occur. Adrenaline, corticosteroids and antihistamines should be used to treat anaphylaxis.

4.4 Special warnings and precautions for use.

Cloxacillin should be given with caution to patients with a history of allergy.

Preparations should be made to deal with anaphylactic shock before the first dose is given.

Care should be taken when administering high doses of cloxacillin especially to patients with impaired renal function as there is a risk of neuro-toxicity and congestive heart failure.

Disturbance of electrolyte balance may occur following administration of large doses. Increases in liver enzyme values have been reported.

Renal and haematological systems should be monitored during prolonged and high dose therapy, patients with syphilis may exhibit the Jarish-Herxheimer reaction and should also therefore be monitored.

A skin test for sensitivity may be used to determine those patients most likely to develop allergic reactions to penicillins.

4.5 Interaction with other medicinal products and other forms of interaction

When concomitantly administered with oral contraceptives, the contraceptives have a reduced effect. Serum concentrations are enhanced if Probenecid is given concomitantly.

4.6 Pregnancy and lactation.

Cloxacillin diffuses across the placenta into the foetal circulation and is excreted in the milk of nursing mothers.

It may provoke allergic reactions in infants that are allergic to penicillins. cloxacillin can be used in pregnant mothers, if necessary

4.7 Effects on ability to drive and use machines.

Not applicable.

4.8 Undesirable effects.

Sensitivity reactions may include skin rashes, angioedema, bronchospasm, serum sickness and anaphylaxis, and sometimes death within minutes. Treatment with adrenaline, corticosteroids, aminophyllin or antihistamines may be necessary. A generalised sensitivity reaction can develop within a few hours or weeks of commencing treatment, including urticaria, fever, joint pains and eosinophilia. Other allergic reactions include exfoliative dermatitis and maculopapular rashes, interstitial nephritis and vasculitis.

Haemolytic anaemia, leucopenia, prolonged bleeding time and defective platelet function can occur.

Oral administration may produce diarrhoea, heartburn and nausea, and hepatitis and cholestatic jaundice have been reported. A sore mouth or tongue, and a black hairy tongue have also been reported.

Supra-infection with C. albicans, other fungi or organisms resistant to cloxacillin may occur.

4.9 Overdose

Convulsions and other signs of toxicity to the central nervous system may occur with very high doses, particularly when administered intravenously to patients with renal failure. Nephrotoxicity may occur in patients with diminished renal function. Treatment of overdosage is symptomatic and supportive.

5. Pharmacological properties

5. Pharmacodynamic properties

Pharmacotherapeutic group: Beta-lactam Antibacterial, Penicillins ATC Code: J01CF02

Cloxacillin Sodium, like other isoxazolyl penicillins, is a potent inhibitor of the growth of most penicillinase-producing staphylococci. This agent, in general, is less effective against micro-organisms susceptible topenicillin G and are not as useful against gram-negative bacteria.

cloxacillin Sodium is bactericidal. It is considered to act by inhibiting transpeptidase, the enzymeresponsible for cross-linking of peptidoglycan during the final stages of synthesis of the bacterial cell wall and so exerts its effects against dividing bacteria. It is active against most gram-positive organisms and neisseria spp.

On the basis of minimum inhibitory concentrations, its activity against both penicillin-resistant and penicillin-sensitive staphylococci is 4 to 8 times that of methicillin sodium, but against penicillin-sensitive staphylococci, its activity is only about one quarter that of benzylpenicillin or phenoxymethyl-penicillin.

A minimum inhibitory concentration against penicillin-resistant staphylococci of 0.25-0.5µg/ml has been reported. Its activityagainst streptococci is less than that of benzylpenicillin but sufficient to be useful when these organisms are present with penicillin-resistant staphylococci.

Resistance to cloxacillin has developed in both penicillinase and non-penicillinase producing staphylococciwith cross resistance to other penicillins, including the penicillinase-resistant penicillins such as cloxacillin, nafcillin and oxacillin; to the cephalosporin's and to other antibiotics including chloramphenicol, erythromycin, tetracycline, kanamycin, streptomycin, and lincomycin. This resistance is intrin sic and unrelated to penicillin production.

5.2 Pharmacokinetic properties

Cloxacillin Sodium is better absorbed from the gastrointestinal tract than cloxacillin sodium but absorptionis also reduced by food in the stomach or small intestine. After an oral dose of 250mg to 500mg, in fasting subjects, peak serum concentrations in about 1 hour may range from 3 to 27µg per ml with mean peak concentrations of about 11 to 15µg per ml. A therapeutic concentration persists for about 4 hours. Doubling the dose can double the plasma concentration. Some 50% of a dose by mouth is excreted in the urine within 6 hours, serum concentrations are enhanced if probenecid is given concomitantly. About 90-95% of Cloxacillin in the circulation is bound to plasma albumin to a greater extent, none is removed from the circulation to a significant degree by haemodialysis. The isoxazolyl penicillins, like cloxacillin, are rapidly excreted by the kidney.There is also significant hepatic elimination of these agents in the bile. The half-life of Cloxacillin is between 30-60 minutes.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6. Pharmaceutical particulars

6.1 List of excipients

Magnesium stearate

Black orange empty shell size 2

6.2 Incompatibilities

None known

6.3 Shelf life

36 months from the date of manufacture

6.4 Special precautions for storage

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

6.5 Nature and contents of container

PVC Blister pack 10×10 in a unit carton with a literature insert/ Bulk Pack of 1000's packed in 1000CC HDPE Container well Labeled**.**

7. Marketing authorization holder

Dawa Limited,

Plot No.7879/8 Baba Dogo Road, Ruaraka

P.O Box 16633-00620 Nairobi –Kenya

8. Registration number(s)

Kenya registration number: H2010/21329/655

Rwanda pre –registration number: N°20/1944/DGCS/PH/2014

9. Legal category: Prescription only medicine, **(POM)**

10. Date of revision of the text

May 2019.