Summary product characteristics:

1. Name of the medicinal product

Dawaclox powder for oral solution

2. Qualitative and quantitative composition

Each 5ml of reconstituted solution contains: Cloxacillin (as sodium) BP 125 mg

For the full list of excipients, see section 6.1

3. Pharmaceutical form: powder for oral solution

A whitish coloured, free flowing granular powder, yields an orange coloured solution on reconstitution

4. Clinical particulars

4.1 Therapeutic indications

Cloxacillin is indicated for the treatment of infections due to gram-positive organisms, including infections caused byp-lactamase producing staphylococci.

Typical indications include: skin and soft tissue infections e.g. boils abscesses, carbuncles, furunculosis, cellulitis, infected wounds, infected burns, protection of skin grafts and impetigo. Infected skin conditions:e.g ulcer, eczema and acne. Respiratory tract infections: Pneumonia, lung abscess, empyema, sinusitis, pharyngitis, tonsillitis, quinsy, otitis media and extema. Other infections caused by cloxacillin-sensitive organisms such as osteomyelitis, enteritis, endocarditis, urinary tract infection, meningitis, septicemia.

4.2 Posology and method of administration

For oral administration.

It should be given at least 30 minutes before meals. Usual oral doses are 250mg to 500mg four times a day.

4.3 Contraindications.

Hypersensitivity to the active substances or to any of the excipients.

4.4 Special warnings and precautions for use.

Desensitization may be attempted if treatment with penicillins is considered essential. Penicillins should be given with caution to patients with a history of allergy, especially to drugs. Care is necessary if very high doses of penicillins are given, especially ifrenal function is poor, because of the risk of neurotoxicity. The intrathecal route should be avoided. Renal, hepatic and haematological status should be monitored during prolonged and high dose therapy. Because of the Jarisch-Herxheimer reaction, care is also necessary when treating patients with spirochaete infections, particularly syphilis. Skin contact with penicillins should be avoided since sensitization may occur. Penicillin therapy changes the normal bacterial flora and can lead to supra-infection with penicillin-resistant organisms including Clostridium difficile or Candida, particularly with prolonged use

4.5 Interaction with other medicinal products and other forms of interaction.

Drug-drug: The possibility of a prolonged bleeding time following oral treatment with a broad spectrum drug like cloxacillin should be borne in mind in patients receiving anticoagulants. Cloxacillin sodium has been reported to be incompatible with aminoglycosides and a number of other antimicrobials. Probenecid increases serum levels of cloxacillin. It may be used for this purpose.

Drug-food: Food decrease drug absorption. Advise taking on an empty stomach. Fruit juices and carbonated beverages may inactivate the drug. Don't give together.

4.6 Pregnancy and lactation.

Cloxacillin has been assigned to pregnancy category B. There are no controlled data on human pregnancies; however, there is no literature reports of congenital abnormalities associated with it. Cloxacillin should only be given when need has been clearly established.

Lactation: Drug is excreted in breast milk and therefore should not be used.

Fertility: No data on the effect of cloxacillin on fertility are available.

4.7 Effects on ability to drive and use machines.

Not applicable.

4.8 Undesirable effects.

CNS: Lethargy, hallucinations, seizures, anxiety, confusion, agitation, depression, dizziness and fatigue. GI: Nausea, vomiting, epigastric distress, diarrhea, enterocolitis, pseudo membranous colitis, black 'hairy' tongue, transient elevations in liver function study results and abdominal pain. Hematologic: eosinophilia, anemia, thrombocytopenia, leucopenia, hemolytic anemia, agranulocytosis. Hepatic: Intrahepatic cholestatis. Others: Hypersensitivity reactions (rash, urticaria, hills, fever, sneezing, wheezing, anaphylaxis), overgrowth of non-susceptible organisms.

4.9 Overdose

Symptoms of over dosage are as per side-effects. Treatment is symptomatic and supportive.

5. Pharmacological properties

5. Pharmacodynamic properties

Cloxacillin exerts a bacterial action against susceptible microorganisms during the stage of active multiplication. It acts through the inhibition of biosynthesis of cell wall mucopeptides. Cloxacillin demonstrates activity against strains of beta-hemolytic streptococci, pneumococci, penicillin G sensitive staphylococci and, due to its resistance to penicillinase, penicillin G resistant (β-lactamase producing) staphylococci. Cloxacillin displays less intrinsic antibacterial activity and a narrower spectrum than penicillin G.

5.2 Pharmacokinetic properties

Cloxacillin is stable in an acid medium and is approximately 50% absorbed orally. After an oral dose of 500mg cloxacillin, a peak serum level of about 8 micrograms/mL is reached in about 1 hour. The serum level after i.m. cloxacillin is approximately twice that obtained when the same dose is given orally to fasting adults. Food in the stomach or small intestine reduces absorption and peak serum levels are approximately 50% those obtained after fasting. As with other penicillins, concurrent administration of probenecid enhances the serum concentration. Once absorbed, approximately 94% are bound to plasma proteins. After oral administration, roughly 20% of the dose is excreted in the urine, together with one or more active metabolites as yet unidentified. The half- life of elimination is about 30 minutes

5.3 Preclinical safety data

Non-clinical data have not revealed significant hazards for humans, based on standard studies of safety pharmacology, repeated-dose toxicity, genotoxicity, carcinogenic potential, and reproductive toxicity. Effects in non-clinical studies were observed only at exposures sufficiently in excess of the maximum human exposure to be of little clinical relevance

6. Pharmaceutical particulars

6.1 List of excipients

Sodium citrate
Citric acid anhydrous
Sodium benzoate
Sodium saccharin
Disodium Edetate
Sunset yellow
Strawberry flavour powder
Xanthan gum
Aerosil
Sucrose

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 direct sunlight. Keep out of reach of children.

6.5 Nature and contents of container

100 ml HDPE Bottle in a unit carton with a literature insert.

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: H2011/21396/454

Rwanda registration number: N°20/DGCS/PH/2014

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

10. Date of revision of the text

May 2019.