Summary of product characteristics.

1.0 Name of the medicinal product

Ampiclo-Dawa powder for oral suspension

2.0 Qualitative and quantitative composition

Each 5ml of the reconstituted suspension contains: Ampicillin (as Trihydrate) BP125mg and
Cloxacillin (as sodium) BP 125mg

3.0 Pharmaceutical form: Dry powder suspension for oral administration.

A whitish coloured, free flowing granular powder yields a yellow coloured suspension on reconstitution, with an orange flavour.

4.0 Clinical particulars

4.1 Therapeutic indications

Respiratory tract infections, urinary tract infections, skin and soft tissue infections, septicemia ,orthopedic infections, ear, nose and throat infections, gastrointestinal infections, pelvic infections and endocarditis.

4.2 Posology and method of administration: For oral administration only.

Dosage
usual adult dosage (including elderly patients): Ear, nose and throat infections:
250 mg four times a day. Bronchitis: Routine therapy: 250 mg four times a day.
High-dosage therapy: 1 g four times a day. Pneumonia:
500 mg four times a day. Urinary tract infections: 500 mg three times a day. Gonorrhoea:
2 g orally with 1 g probenecid as a single dose.
Repeated doses are recommended for the treatment of females. Gastro-intestinal infections:
500-750 mg three to four times daily.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients.
Use in patients with a history of hypersensitivity to beta lactam antibiotics (Penicillins, and cephalosporins) or any of the excipients.

4.4 Special warnings and precautions for use

Before initiating therapy with ampicillin, careful enquiry should be made concerning previous hypersensitivity reactions to beta-lactam antibiotics.
Serious and occasionally fatal hypersensitivity reactions (anaphylaxis) have been reported in patients receiving beta-lactam antibiotics. Although anaphylaxis is more frequent following parenteral therapy, it has occurred in patients on oral pencillins. These reactions are more likely to occur in individuals with a history of beta-lactam hypersensitivity.
Ampicillin should be avoided if infectious mononucleosis and/or acute or chronic leukaemia of lymphoid origin are suspected. The occurrence of a skin rash has been associated with these conditions following the administration of ampicillin.

4.5 Interaction with other medicinal products and other forms of interaction

Bacteriostatic drugs may interfere with the bactericidal action of ampicillin. In common with other oral broad-spectrum antibiotics, ampicillin may reduce the efficacy of oral contraceptives and patients should be warned accordingly.
Probenecid decreases the renal tubular secretion of ampicillin. Concurrent use with ampicillin may result in increased and prolonged blood levels of ampicillin.
Concurrent administration of allopurinol during treatment with ampicillin can increase the likelihood of allergic skin reactions. It is recommended that when testing for the presence of glucose in urine during ampicillin treatment, enzymatic glucose oxidase methods should be used. Due to the high urinary concentrations of ampicillin, false positive readings are common with chemical methods.

4.6. Pregnancy and lactation
Pregnancy: Animal studies with ampicillin have shown no teratogenic effects. The product has been in extensive clinical use since 1961 and its use in human pregnancy has been well documented in clinical studies. When antibiotic therapy is required during pregnancy, ampicillin may be considered appropriate.
Lactation: During lactation, trace quantities of penicillins can be detected in breast milk. Adequate human and animal data on use of ampicillin during lactation are not available.

4.7 Effects on ability to drive and use machines.
Adverse effects on the ability to drive or operate machinery have not been observed.

4.8 Undesirable effects.
Hypersensitivity reactions: If any hypersensitivity reaction occur, the treatment should be discontinued
Skin rash, pruritis and urticaria have been reported occasionally. The incidence is higher in patients suffering from infectious mononucleosis and acute or chronic leukaemia of lymphoid origin. Purpura has also been reported. Rarely, skin reactions such as erythema multiforme and Stevens-Johnson syndrome, and toxic epidermal necrolysis have been reported.
As with other antibiotics, anaphylaxis has been reported rarely.
Renal effects: Interstitial nephritis can occur rarely.
Gastrointestinal reactions: Effects include nausea, vomiting and diarrhoea. Pseudomembranous colitis and haemorrhagic colitis has been reported rarely.
Hepatic effects:
As with other beta-lactam antibiotics, hepatitis and cholestatic jaundice have been reported rarely. As with most other antibiotics, a moderate and transient increase in transaminases has been reported.
Haematological effects:
As with other beta-lactams, haematological effects including transient leucopenia, transient thrombocytopenia and haemolytic anaemia have been reported rarely. Prolongation of bleeding time and prothrombin have also been reported rarely.

4.9 Overdose.
Gastrointestinal effects such as nausea, vomiting and diarrhoea may be evident and should be treated symptomatically. Ampicillin may be removed from the circulation by haemodialysis

5. 0 Pharmacological properties
5.1 Pharmacodynamic properties.
Ampicillin 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. Ampicillin has in vitro activity against gram-positive and gram-negative aerobic and anaerobic bacteria. The bactericidal activity of Ampicillin results from the inhibition of cell wall synthesis and is mediated through Ampicillin binding to penicillin binding proteins (PBPs). Ampicillin is stable against hydrolysis by a variety of beta-lactamases. By including penicillinases, and cephalosporinases and extended spectrum beta-lactamases. By binding to specific penicillin-binding proteins (PBPs) located inside the bacterial cell wall, Ampicillin inhibits the third and last stage of bacterial cell wall synthesis. Cell lysis is then mediated by bacterial cell wall autolytic enzymes such as autolysins; it is possible that Ampicillin interferes with an autolysin inhibitor. Cloxacillin is a semisynthetic antibiotic in the same class as penicillin. Cloxacillin is for use against staphylococci that produce beta-lactamase. By binding to specific penicillin-binding proteins (PBPs) located inside the bacterial cell wall, Cloxacillin inhibits the third and last stage of bacterial cell wall synthesis.
Cell lysis is then mediated by bacterial cell wall autolytic enzymes such as autolysins; it is possible that Cloxacillin interferes with an autolysin inhibitor.

5.2 Pharmacokinetic properties
Absorption: The oral administration of 250 mg and 500 mg of ampicillin on a fasting stomach produces maximum serum levels of ± 2 and ± 4 mcg per ml, respectively, after 2 hours. Bioavailability is 30 to 40%. The absorption of orally administered ampicillin can be diminished by food. Distribution: Serum protein binding ampicillin is about 20 %. Plasma half-life is between 1 and 1 ½ hours. Ampicillin diffuses into most tissues and body fluids. Its presence in therapeutic concentrations has been detected in, among others, bronchial secretions sinuses, saliva, CSF (variable percentage depending on the degree of meningeal inflammation), bile, serous membranes and middle ear. Crosses the meningeal barrier: There is little ampicillin diffusion into the cerebrospinal fluid, except in cases of inflamed meninges, in which it can reach therapeutic concentrations when administered in high doses and especially by the intravenous route. Cross the placenta: Ampicillin diffuses through the placenta. Passes into mother's milk: Ampicillin is detected in small quantities in mothers' milk. Metabolism and Excretion: Ampicillin is eliminated chiefly through the urine. Approximately 30% of the dose administered orally and over 60 % of the dose administered parenterally are eliminated in active form in the urine during the 24 hours which follow the administration of ampicillin. Urinary concentrations are higher following parenteral administration. A small percentage is eliminated in the bile where high concentrations are found. Excretion may be delayed in cases of renal failure in accordance with its severity

5.3 Preclinical safety data: Not applicable
6.0 Pharmaceutical particulars
6.1 List of excipients
Sunset yellow colour
Sodium benzoate
Sodium citrate Anhydrous
Sodium CMC
Aerosil
Strawberry flavor powder
Disodium Edetate,
Sodium saccharin
Sucrose (commuted and dried)
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 30ºC, protected direct sunlight. Keep all medicines out of reach of children.

6.5 Nature and contents of container:
100ml white coloured HDPE bottles in a unit box alongside with leaflet
6.6 Special precautions for disposal and other handling
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7.0 Marketing authorisation holder
Dawa Limited,
Plot No. 7879/8, Baba Dogo Road, Ruaraka,
P.O Box 16633-00620, Nairobi, Kenya.

8. Manufacturer:
Dawa Limited,
Plot No. 7879/8, Baba Dogo Road, Ruaraka,
P.O Box 16633-00620, Nairobi, Kenya.

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

10. Date of revision of the text:
January 2020