1.4 product information
1.4.1 Prescribing information (Summary of product characteristics)
1. Name of the medicinal product
Kloxy dry syrup
2. Qualitative and quantitative composition
Each 5mL when reconstituted Contains: Cloxacillin Sodium BP equivalent to 125mg Cloxacillin and excipients in section 6.1.
3. Pharmaceutical form
Powder for oral Suspension
Off-white, granular powder that forms a reddish pink syrup on reconstitution with water, packed in 100ml amber glass/ HDPE bottle and contained in a unit box with literature insert.
4. Clinical particulars
4.1 Therapeutic indications.
Kloxy or Cloxacillin is indicated in the treatment of infections caused by sensitive organisms outlined above and primarily in infections due to staphylococci resistant to benzyl penicillin such as commonly occurs in bone and joint infections, endocarditis, pneumonia, toxic shock syndrome, peritonitis often associated with continuous ambulatory peritoneal dialysis and skin infections including soft tissue infections.
4.2 Posology and method of administration
When administered orally it should be given at toast 30 minutes before meals to facilitate absorption.
Kloxy or Cloxacillin may be given with other antibacterial including ampicillin so as to produce a wider spectrum of antimicrobial activity. Kloxy or Cloxacillin capsules and suspension are administered orally.
Usual adult doses are 500mg of Cloxacillin 4 times daily by mouth. Children up to 2 years of age may be given one quarter the adult dose and those aged 2 to 10 years one-half the adult dose.
All these systemic doses may be doubled in severe infections.
4.3 Contraindications
Oral route of administration
4.4 Special warnings and precautions for use.
1. Older patients and those receiving treatment for more than 2 weeks are at a greater risk of developing hepatitis and cholestatic jaundice.
2. Use of isoxazolyl penicillins have in rare cases been associated with agranulocytosis and neutropenia.
3. Kloxy or Cloxacillin preparations are contraindicated in patients hypersensitive to penicillin and should be given with caution to patients with known histories of allergy.
4. Anaphylactic reactions when they develop and manifesting as urticaria hypotension or shock are best treated with parenteral adrenaline and antihistamines.
4.5 Interaction with other medicinal products and other forms of interaction
1. As with most penicillins the most common adverse effects are hypersensitivity reactions especially skin rashes, while nausea and diarrhea are the more likely gastrointestinal effects to occur. Also as is common with the use of most antibiotics, pseudomembranous colitis may be experienced.
2. Patients with impaired renal function may experience the following adverse effects;
(a) Electrolyte disturbances;
(b) Prolonged bleeding time and defective platelet function;
(c) Haemolytic anaemia and neutropenia;
(d) Convulsions and other signs of CNS toxicity. ·
3. Patients with syphilis or other spirochaete infections may experience a Jarisch-Herxheimer reaction shortly after initiating treatment.
4. Other side effects that occur occasionally are sore throat or tongue or a black hairly tongue, neutropenia, interstitial nephritis and anaphylaxis, the extreme hypersensitivity reaction which may be fatal if it occurs.
4.6 Pregnancy and lactation
Cloxacillin has been assigned to pregnancy category B. There are no controlled data in human pregnancies; however, there are no literature reports of congenital abnormalities associated with it. Cloxacillin should only be given during pregnancy when need has been clearly established.

There are no data on the excretion of Cloxacillin into human milk. Other penicillins are excreted into human milk in small amounts. Adverse effects in the nursing infant are unlikely.

4.7 Effects on ability to drive and use machines

No effects on the ability to drive and to use machines have been observed.

4.8 Undesirable effect

As with most penicillins, the most common adverse effects are hypersensitivity reactions especially skin rashes, while nausea and diarrhoea are the more likely gastrointestinal effects to occur. In addition, as is common with use of most antibiotics, pseudomembranous colitis may be experienced Patients with impaired renal function may experience the following adverse effects (a) Electrolyte disturbances

(b) Prolonged bleeding time and defective platelet function

(c) Haemolytic anaemia and neutropenia

(d) Convulsions and other signs of CNS toxicity

Patients with syphilis or other spirochaette infections may experience a jarish-herxheimer reaction shortly after initiating treatment.

Other side effects that occur occasionally are sore throat/ tongue or a black hairy tongue, neutropenia, interstitial nephritis and anaphylaxis, the extreme hypersensitivity reaction which may be fatal if it

4.9 Overdose

Seek emergency medical treatment or contact the doctor in case of an overdose

- Major & minor side effects for Cloxacillin
- Nausea and Vomiting.
- Diarrhea.
- Abdominal pain.
- Sore mouth and tongue.
- Yellowing of skin and eyes.
- Flatulence.
- Wheezing.
- Rash.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: (Antibiotic penicillin)

ATC code: J01CF02

Kloxy preparations contain Cloxacillin, which is an isoxazolyl beta lactam penicillin antibiotic with bactericidal action against Gram-positive bacteria, Gram-negative cocci, some other Gram-negative bacteria, spirochaetes and aminomycetes.

Cloxacillin exerts its antibacterial action against growing and dividing bacteria mostly by inhibiting cell-wall formation through inhibition of peptidoglycan production.

Peptidoglycans hold bacterial cell walls rigid and protect then against osmotic rupture. Cloxacillin binds to and inactivates transpeptidases on the inner surface of the bacterial cell membranes. Transpeptidases are penicillin-binding proteins, which are involved in the final cross-linking stage of peptidoglycan synthesis. Other mechanisms of bacterial lysis are also involved in the bacterial activity of Cloxacillin.

ANTIMICROBIAL SPECTRUM OF ACTIVITY:

The following bacteria are sensitive to Cloxacillin:

Bacillus anthracis, Clostridium perfringens, Cl. tetani. Corynebacterium diphtheriae, Erysipelothrix rhusiopathiae, listeria monocytogenes, Peptostreptococcus spp., Penicillinase, and non-penicillinase producing staphylococci, Streptococcus agalactiae (group B), Str.pyogenes, pneumococcus, some viridians streptococcus, meningococcus, gonococcus, Prevotella spp. {non-fragilis bacteriodes), Fusobacterium spp., Pasturella multocida, Streptobacillus minus (or minor), some strains of Proteus mirabilis and some strains of Escherichia coli. Other organisms sensitive to Cloxacillin include Actinomycetes and the spirochaetes: Borrelia, Leptospira and Treponema spp.

5.2 Pharmacokinetic properties

When given orally Cloxacillin is incompletely absorbed from the gastro-intestinal tract and the presence of food in the stomach or small intestines reduces absorption even further. Cloxacillin is better absorbed through the intramuscular route when a peak plasma concentration of 15g/ml is achieved within 30 minutes on administration of a 500mg dose. By comparison, a peak plasma concentration of 7-14 µg/ml is achieved only after 1-2 hours of the same oral dose given to a fasting patient. Doubling the dose can double the plasma concentration. Plasma concentration may also be enhanced by administering probenecid concomitantly.

About 94% of the Cloxacillin in circulation is bound to plasma proteins and have a plasma half-life of about ½ to 1 hour. In neonates, the half-life is prolonged. Cloxacillin diffuses into CSF only when the meninges is inflamed and appears in breast milk, pleural fluid, synovial fluid, in bone and foetal blood circulation. Mostly the unchanged drug and metabolites are excreted by glomerular filtration and renal tubular secretion. Of an oral dose, about 10% is excreted in bile.

5.3 Preclinical data safety

Not Applicable

6. Pharmaceutical particulars

6.1 List of excipients

Sodium Benzoate Powder
Sodium Citrate
Sodium Saccharin
Disodium Edetate (EDTA)
Sodium CMC
Xanthan Gum
Aspartame
Aerosil 200 Pharma
Vanilla Flavour Powder
Magnesium stearate
Carmoisine colour
Banana powder
Menthol
Isopropyl Alcohol 99%

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 Months

6.4 Special precautions for storage

Store in a dry place below 30°C.
Protect form light.
Replace cap tightly after use
Keep all medicines out of reach of children.

6.5 Nature and contents of container

Off-white, granular powder that forms a reddish pink syrup on reconstitution with water, packed in 100ml amber glass/ HDPE bottle and contained in a unit box with literature insert.

6.6 Special precautions for disposal and other handling

No special requirements.

7. Marketing Authorization Holder and Manufacturing Site Addresses Marketing Authorization Holder:

Company Name: LABORATORY & ALLIED LTD
Address: Plot No. 209/10349, Opposite Sameer Business Park, Next to Libra House, Mombasa road,

P.O. Box 42875 GPO 00100, Nairobi,
Country : Kenya
Telephone : +254 20 8040306
Telefax : +254 20 8040309
E-Mail : info@laballied.com.

Manufacturing Site Address:
Company Name: LABORATORY & ALLIED LTD
Address: Plot No. 209/10349, Opposite Sameer Business Park, Next to Libra House, Mombasa road, P.O. Box 42875 GPO 00100, Nairobi,
Country : Kenya
Telephone : +254 20 8040306
Telefax : +254 20 8040309
E-Mail : info@laballied.com

8. Marketing Authorization Number:
Kenya: H95/196

9. Date of first Registration/ Renewal of the Registration:
Kenya: 07/30/1995

10. Date of revision of the text:
May 2023