# SANCLOX 500 POWDER FOR INJECTION SUMMARY OF PRODUCT CHARACTERISTICS

**1.3 Product Information**

**1.3.1 SPC, Labeling and Package Leaflet**

**1. Name of the Medicinal Product**

**SANCLOX- 500** (Ampicillin and Cloxacillin for Injection 500 mg)

**2. Qualitative and Quantitative Composition**

Each vial contains:

Ampicillin Sodium BP eq. to anhydrous Ampicillin 250 mg

Cloxacillin Sodium BP eq. to Cloxacillin 250 mg

**3. Pharmaceutical Form**

Dry Injection

**4. Clinical Particulars**

**4.1 Therapeutic indications**

SANCLOX -500 (Ampicillin and Cloxacillin for Injection 500 mg) is used to treat respiratory tract infections, ear, nose and throat infections, pelvic infections, urinary tract infections, skin and soft tissue infections, and gastrointestinal infections.

This combination of 2 antibiotics is the drug of choice for Metritis, Retained Placenta, Mastitis , Septicaemia, systemic and local infections, chronic wounds, abscesses, enteritis, post surgical therapy, pyrexia of unknown origin, (Pneumonia. It is active against both Gm +ve and Gm -ve organisms.

**4.2 Contra-Indications:**

Penicillin hypersensitivity; ocular administration. Attention should be paid to possible cross-sensitivity with other beta-lactam antibiotics, e.g. cephalosporins, penicillins.

**4.3 Side Effects**

**Ampicillin and Cloxacillin for Injection** may produce diarrhoea, nausea and heartburn. Allergic reactions which may include exfoliative dermatitis, other skin rashes, interstitial nephritis and vasculitis may occur. In this event, withdrawal of **Ampicillin and Cloxacillin for Injection** and administration of an antihistamine will suffice in most cases. Should a serious anaphylactic reaction occur. **Ampicillin and**

**Cloxacillin for Injection** should be discontinued and the patient treated with the usual agents (adrenalin, corticosteroids or antihistamines).

A generalised sensitivity reaction with urticaria, fever, joint pains and eosinophilia can develop within a few hours to several weeks after starting treatment. Superinfections by resistant species, such as Pseudomonas or Candida, which do not respond to penicillin therapy may occur.

A sore mouth or tongue and a black hairy tongue have been reported. Increase in liver enzyme values have been reported.

## 4.4 Adverse Reactions

The following statements reflect the information available on the adverse reaction profile of the individual constituents (ampicillin and cloxacillin) and/or the combination in Ampicillin and Cloxacillin for Injection.

The majority of the adverse reactions listed below are not unique to Ampicillin and Cloxacillin for Injection and may occur when using other penicillins.

Adverse reactions are listed below by system organ class and frequency.

Frequencies are defined as: very common (>1/10), common (>1/100, <1/10), uncommon (>1/1000, <1/100), rare (>1/10,000, <1/1000), very rare (<1/10,000), including isolated reports.

Common and uncommon adverse reactions were generally determined from pooled safety data from a clinical population of 1210 treated patients. Rare and very rare adverse reactions were generally determined from more than 32 years of post-marketing experience data and refer to reporting rate rather than true frequency.

**Blood and lymphatic system disorders**

Very rare:

Haemolytic anaemia,

leucopenia, thrombocytopenia and agranulocytosis.

**Immune system disorders**

Very rare:

Anaphylaxis (see item 4.4 Warnings) and other hypersensitive reactions.

Skin disorders and interstitial nephritis have been reported as hypersensitivity reactions.

If any hypersensitivity reaction occurs, the treatment should be discontinued.

**Nervous system disorders**

Very rare:

Myoclonus and convulsions.

**Gastrointestinal disorders**

Common:

Diarrhoea and nausea.

Uncommon: Vomiting.

Very rare:

Pseudomembranous colitis and haemorrhagic colitis.

**Hepato-biliary disorders**

Very rare:

Hepatitis and cholestatic jaundice. A moderate and transient increase in transminases.

**Skin and subcutaneous tissue disorders**

Common:

Skin rash, urticaria and pruritus. The incidence of skin rash, pruritus and urticaria is higher in patients suffering from infectious mononucleosis and acute or chronic leukaemia of lymphoid origin.

Very rare:

Bullous reactions (including erythema multiforme, Stevens-Johnson syndrome and toxic epidermal necrolysis), exfoliative dermatitis and purpura. Skin disorders have also been reported as hypersensitivity reactions.

**Renal and urinary disorders**

Very rare:

Interstitial nephritis.

Interstitial nephritis has also been reported as a hypersensitivity reaction.

## 4.5 Antidote in the events of Overdosage

Overdosage with oral ampicillin - cloxacillin is unlikely to cause serious reactions if renal function is normal. Very high dosage of i.v. administered ampicillin and/or high dosage of cloxacillin in renal failure may provoke neurotoxic reactions similar to those seen with benzylpenicillin in excess. Gastrointestinal effects such as nausea, vomiting and diarrhoea may be evident. Gastrointestinal effects should be treated symptomatically. Further management should be as clinically indicated or as recommended by the national poisons centre, where available.



## 4.6 Indications for Ampicillin + Cloxacillin

Ampicillin has a narrow spectrum of activity and is mainly active againstGram positive bacilli, both gram positive and Gram negative cocci and spirochaetes. Cloxacillin has a similar spectrum of activity to Penicillin and it is also active against penicillinase producing organisms such as staphylococcus aureus.

1.Respiratory tract infection

2.Urinary tract infection

3.Bone and joint infection

4.Skin infection

5.Soft tissue infection

## 5. Pharmacological properties

### 5.1 Pharmacodynamic properties

Ampicillin exerts bactericidal action on both gm+ve and gm-ve organisms. Its spectrum includes gm+ve organisms eg, S pneumoniae and other Streptococci, L monocytogenes and gm-ve bacteria eg, M catarrhalis, N gonorrhoea, N meningitidis, E coli, P mirabilis, Salmonella, Shigella, and H influenzae. Ampicillin exerts its action by inhibiting the synthesis of bacterial cell wall. Cloxacillin is a penicillinase-resistant penicillin. It is active against gm+ve organisms including penicillinase-producing strains of Staphylococci. Cloxacillin is highly active against Staph aureus, Strep pyogenes, Strep viridans and Strep pneumoniae. It is also active against penicillinase-producing gonococci and against N meningitidis and H influenzae. Other gm-ve organisms are resistant to cloxacillin as are also methicillin-resistant strains of Staphylococci.

### 5.2 Pharmacokinetic properties



Oral

Susceptible infections:

Adult- Per Cap contains ampicillin 250mg & Cloxacillin 250mg, one cap four times daily.

In severe infections, the dose can be increased up to 12 caps daily.

Child- Per dose contains ampicillin 125mg, & cloxacillin 125mg: one dose four times daily.

Skin & soft tissue infections osteomyelitis & other bone infections:

Adult- In acute osteomyelitis parenteral therapy for first three weeks for another three weeks in chronic osteomyelitis parenteral therapy for one – two months followed by oral therapy subsequently.

Intravenous:

Severe Infections:

Septicaemia, meningitis endocarditis caused by sensitive pathogens.

Adult- 500mg (Ampicillin 250mg & Cloxacillin 250mg) in ten ml or 1g (ampicillin 500mg & cloxacillin 500mg)

in 20 ml of water for injections. Given slowly over three to four minutes,

repeated every six hours.
Doses higher than 500mg should be given in two different sites of not more than 500mg in 3ml.

Intramuscular
Moderate to severe infections
Adult: 500 mg (ampicillin 250 mg and cloxacillin 250 mg) or 1 g (ampicillin 500 mg and cloxacillin 500 mg) every 6 hr. Doses higher than 500 mg should be given in two different sites of not more than 500 mg in 3ml.

Intramuscular
Severeinfections
Adult: 500 mg (ampicillin 250 mg and cloxacillin 250 mg) or 1 g (ampicillin 500 mg and cloxacillin 500 mg) every 6 hr. Doses higher than 500 mg should be given in two different sites of not more than 500 mg in 3ml.



**6.1 List of excipients**

Not applicable

**6.2 Incompatibilities**

None known

**6.3 Shelf life**

3 years

**6.4 Special precaution for storage**

Store in a cool place.
Protect from light.

**6.5 Nature contents of container**

5 ml flint glass vial

**6.6 Instruction for use handling and disposal**

Keep out of reach of children.

**7. Marketing authorization holder**

De Santos Pharm. Co. Ltd.,
12B, Isunjaba Street, Awada Obosi,
Onitsha, Anambra State, Nigeria

**8. Marketing authorization number ( s)**
**04-5390**

**9. Date of first authorization / renewal of authorization**
**28th April, 2016**

**10. Date of revision of the text**
**August 2023**