APPROVED PATIENT INFORMATION LEAFLET

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KLOJECT 250 mg INJECTION (Powder for injection)

KLOJECT 500 mg INJECTION (Powder for injection)

1. WHAT KLOJECT INJECTION CONTAINS

The active substance is cloxacillin.

KLOJECT 250 mg INJECTION:

Each vial contains cloxacillin sodium equivalent to cloxacillin 250 mg.

KLOJECT 500 mg INJECTION:

Each vial contains cloxacillin sodium equivalent to cloxacillin 500 mg.

Read all of this leaflet carefully before you are given KLOJECT.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **KLOJECT** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

2. WHAT KLOJECT INJECTION IS USED FOR

KLOJECT INJECTION is an antibiotic in the class of medicines called penicillins. It is used to treat bacterial infections of the skin, bone, blood, heart valve, heart's inner lining and lungs.

3. BEFORE YOU RECEIVE KLOJECT INJECTION

Do not receive KLOJECT INJECTION:

- If you have ever had an allergic reaction to another penicillin or to a cephalosporin antibiotic or any other ingredients of **KLOJECT INJECTION**.
- If the patient is a newborn baby whose mother is allergic to penicillin.

- **KLOJECT INJECTION** should not be used as an eye drop.

Take special care with KLOJECT INJECTION:

- If the patient is a newborn baby with jaundice (yellowing of the skin or the whites of the eyes).
- Use of **KLOJECT INJECTION** may result in oral thrush or a new vaginal yeast infection (oral or vaginal fungal infection). Contact your doctor if you notice white patches in your mouth, a change in vaginal discharge or other new symptoms.
- During long-term treatment and with high doses, your doctor may want to monitor your kidney function and blood.
- Your doctor may decide to perform a skin test for allergy, to determine if you are likely to develop an allergic reaction to penicillins.
- Tell your doctor if you have kidney problems.
- Tell your doctor if you have syphilis.

Pregnancy and Breast-feeding:

The safety of **KLOJECT INJECTION** in pregnant and breast-feeding mothers has not been established. **KLOJECT INJECTION** passes into breast milk.

If you are pregnant or breast-feeding your baby please consult your doctor, pharmacist or other health care professional for advice before taking this medicine.

Taking other medicines with KLOJECT INJECTION:

Some medicines may interact with **KLOJECT INJECTION**. Before taking **KLOJECT INJECTION**, tell your doctor if you are using any of the following medicines:

- chloramphenicol (an antibiotic)
- tetracyclines (a class of antibiotics)
- blood thinning medication e.g. warfarin
- methotrexate – an immune suppressant medicine
- oral contraceptives – **KLOJECT INJECTION** may decrease the effectiveness of birth control pills. Use a second method of birth control while taking **KLOJECT INJECTION** to protect against pregnancy.

- other medications injected into a vein such as aminoglycosides, erythromycin and polymixin B.

If you are using any of these medicines, you may not be able to take **KLOJECT INJECTION**, or you may need dosage adjustments or your doctor may need to monitor you carefully for side-effects.

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

4. HOW TO RECEIVE KLOJECT INJECTION

- **KLOJECT INJECTION** is given as an injection.
- Your doctor will prescribe an appropriate dose according to your conditions.

If you have the impression that the effect of **KLOJECT INJECTION** is too strong or too weak, talk to your doctor or pharmacist.

If you receive more KLOJECT INJECTION than you should:

Overdose symptoms may include seizures (convulsions).

Since a healthcare professional will administer **KLOJECT INJECTION**, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to receive KLOJECT INJECTION:

- Your medication will usually be given to you by a healthcare professional. If you think you may have missed a dose, please tell your doctor or nurse.

5. POSSIBLE SIDE-EFFECTS

KLOJECT INJECTION can have side-effects.

If any of the following happens, tell your doctor immediately or go to the casualty department at your nearest hospital:

- Hives; difficulty breathing; swelling of your face, lips, tongue, or throat; fever; joint pains; red, scaly skin; skin rash (angioedema).
- Fits

Call your doctor at once if you have any of these serious side-effects:

- Fever, chills, sore throat, or other signs of infection.
- Unusual tiredness
- Unusual bleeding or bruising
- Decreased amount of urine

Tell your doctor if you notice any of the following side-effects and they worry you or if any of these symptoms are severe or do not go away:

- White patches on the tongue (thrush/yeast infection)
- Itching or discharge of the vagina (vaginal yeast infection)

Not all side-effects reported for **KLOJECT INJECTION** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving **KLOJECT INJECTION**, please consult your doctor, pharmacist or other health care professional for advice.

6. STORING AND DISPOSING OF KLOJECT INJECTION

Dry Powder: Store at or below 25 °C (room temperature).

Solutions: Solutions for injection should preferably be freshly prepared, but must be used within 24 hours if stored at room temperature or within 4 days if stored in the refrigerator (at 4 °C).

KLOJECT INJECTION is usually stored and handled by a healthcare provider. If you are using **KLOJECT INJECTION** at home, store **KLOJECT INJECTION** as directed by your pharmacist or healthcare provider.

Store all medicines out of reach of children.

7. PRESENTATION OF KLOJECT INJECTION

KLOJECT 250 mg INJECTION:

15 ml Type-I Ph.Eur. moulded glass vials fitted with 20 mm grey colour bromo butyl rubber stoppers and sealed with 20 mm yellow colour flip off seal.

Pack sizes:

1. Single vial packed in printed carton with a package insert.
2. Ten vials are packed in printed carton with a package insert.

KLOJECT 500 mg INJECTION:

15 ml Type-I Ph.Eur. moulded glass vials fitted with 20 mm grey colour bromo butyl rubber stoppers and sealed with 20 mm light blue colour flip off seal.

Pack sizes:

1. Single vial packed in printed carton with a package insert.

2. Ten vials are packed in printed carton with a package insert.

8. IDENTIFICATION OF KLOJECT INJECTION

A white or almost white powder. When reconstituted, a clear, colourless solution is formed.

9. REGISTRATION NUMBERS/REFERENCE NUMBERS

BAKARA 250 mg: 44/20.1.2/0473

BAKARA 500 mg: 44/20.1.2/0474

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Aurogen South Africa (Pty) LTD

Woodhill Office Park, Building 1,

53 Phillip Engelbrecht Avenue

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11. DATE OF PUBLICATION

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