APPROVED PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.

- If you have further questions, please ask your doctor or your pharmacist.

- This medicine 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.

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1. AURO CEFOTAXIME 250 mg (Powder For Injection)
2. AURO CEFOTAXIME 500 mg (Powder For Injection)
3. AURO CEFOTAXIME 1000 mg (Powder For Injection)
4. AURO CEFOTAXIME 2000 mg (Powder For Injection)

Cefotaxime Sodium equivalent to Cefotaxime

1. WHAT AURO CEFOTAXIME CONTAINS

The active substance is Cefotaxime Sodium.

1. Each vial contains Cefotaxime Sodium equivalent to **Cefotaxime 250 mg**.
2. Each vial contains Cefotaxime Sodium equivalent to **Cefotaxime 500 mg**.
3. Each vial contains Cefotaxime Sodium equivalent to **Cefotaxime 1000 mg**.
4. Each vial contains Cefotaxime Sodium equivalent to **Cefotaxime 2000 mg**.

2. WHAT AURO CEFOTAXIME IS USED FOR

AURO CEFOTAXIME is indicated for the treatment of infections caused by susceptible strains of organisms in the following infections:-

Upper Respiratory Tract Infections:

- Pneumococcal infections – Pneumonia, bronchitis, cellulites, otitis media

- *Haemophilus influenzae* infections – Otitis media, laryngotracheobronchitis, meningitis (in children)

Urinary tract infections:

- E.coli infections – Pneumonia, urinary tract infections, meningitis (in children)

Gastrointestinal Infections:

- Shigella infections – Bacillary dysentery
- Salmonella infections – Enteritis

Other:

- *Neisseria meningitides* – Meningitis (in children)
- Acute uncomplicated cystitis caused by *E. coli* and *Klebsiella pneumoniae.*

Note: Bacteriological tests to determine causative organisms and sensitivities are recommended.

AURO CEFOTAXIME is indicated perioperatively to reduce the incidence of post-operative infections in patients undergoing surgical procedures classified as potentially contaminated.

3. BEFORE YOU TAKE AURO CEFOTAXIME

Do not take AURO CEFOTAXIME:

If you are hypersensitive (allergic) to cefotaxime, cephalosporin or any of the other ingredients of **AURO CEFOTAXIME.**

If you are hypersensitivity (allergic) to penicillin and other beta-lactam antibiotics

Take special care with AURO CEFOTAXIME (Powder for injection):

- If you have a history of gastrointestinal disease, especially ulcerative colitis, regional enteritis or antibiotic-associated colitis.
- If you have been diagnosed with renal function impairment – A reduced dose may be required.
- Porphyria: Safety has not been established.

Pregnancy and Breast-feeding:

Safety of **AURO CEFOTAXIME** in pregnant and lactating women has not been established.

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

Taking other medicines with AURO CEFOTAXIME:

- Concurrent administration of potentially nephrotoxic medicines or diuretics may increase the risk of possible nephrotoxicity.
- A positive Coombs reaction appears in patients who receive large doses of **AURO CEFOTAXIME**.
- Haemolysis is not usually associated with the phenomenon but it may interfere with cross-matching of blood.

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **AURO CEFOTAXIME** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

4. HOW TO TAKE AURO CEFOTAXIME

Always take **AURO CEFOTAXIME** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **AURO CEFOTAXIME** is too strong or too weak, talk to your doctor or pharmacist.

AURO CEFOTAXIME is administered intravenously (i.e. in the blood) or IM (i.e. into the muscle) as directed by your doctor.

If you take more AURO CEFOTAXIME than you should:

Symptoms of overdose:

Encephalopathy (impairment of consciousness, abnormal movements and seizures) has been reported.

Treatment of overdose:

Treatment is symptomatic and supportive

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control center.

5. POSSIBLE SIDE EFFECTS

AURO CEFOTAXIME can have side effects.

Blood and lymphatic system disorders

Frequent: eosinophilia,

Less frequent: haemolytic anaemia, neutropenia, thrombocytopenia (reversible)

The following side effects have been reported and frequencies are unknown: Agranulocytosis

Cardiovascular disorders

The following side effects have been reported and frequencies are unknown:

Arrhythmias following rapid bolus infusion through a central venous catheter

Nervous system disorders

Frequent: headache

The following side effects have been reported and frequencies are unknown:

*confusion, *encephalopathy

Gastrointestinal disorders

Frequent: diarrhoea, nausea, vomiting, abdominal pain

Renal and urinary disorders

*Less frequent: d*ecrease in renal function (especially when co-prescribed with aminoglycosides), *The following side effects have been reported and frequencies are unknown: **interstitial nephritis

Hepato-biliary disorders

The following side effects have been reported and frequencies are unknown: Transient increases in hepatic enzyme levels and / or bilirubin (Values may exceed twice the upper limit of normal and lead to asymptomatic cholestatic liver injury.)

Skin and subcutaneous tissue disorders

Less frequent: rash, pruritus, urticaria, erythema multiforme, Stevens Johnson syndrome, toxic epidermal necrolysis

General disorders and administration site conditions

Less frequent: * local inflammatory reactions at the injection site

Immune system disorders

Less frequent: Hypersensitivity reactions including skin rashes, urticaria, pruritus, bronchospasm, drug fever, serum sickness, shock, anaphylaxis

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

6. STORING AND DISPOSING OF AURO CEFOTAXIME

Keep all medicines out of the reach and sight of children.

Store below 25 °C. Protect from light.

Keep the vials in the carton until required for use.

Discard any unused portion of the re-constituted solution in the vial.

KEEP OUT OF REACH OF CHILDREN.

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Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF AURO CEFOTAXIME

1. **AURO CEFOTAXIME 250 mg** – Single clear glass vial packed in printed carton with a package insert.
2. **AURO CEFOTAXIME 500 mg** – Single clear glass vial packed in printed carton with a package insert.
3. **AURO CEFOTAXIME 1000 mg** – Single clear glass vial packed in printed carton with a package insert.
4. **AURO CEFOTAXIME 2000 mg** – Single clear glass vial packed in printed carton with a package insert.

8. IDENTIFICATION OF AURO CEFOTAXIME

1. **AURO CEFOTAXIME 250 mg** – A white or slightly yellow powder filled in Type-I 15 ml moulded clear glass vial fitted with 20 mm bromo butyl rubber stopper and sealed with 20 mm light brown flip off aluminium seal.
2. **AURO CEFOTAXIME 500 mg** – A white or slightly yellow powder filled in Type-I 15 ml moulded clear glass vial fitted with 20 mm bromo butyl rubber stopper and sealed with 20 mm light green flip off aluminium seal.
3. **AURO CEFOTAXIME 1000 mg** – A white or slightly yellow powder filled in Type-I 15 ml moulded clear glass vial fitted with 20 mm bromo butyl rubber stopper and sealed with 20 mm lime green flip off aluminium seal.

4. **AURO CEFOTAXIME 2000 mg** – A white or slightly yellow powder filled in Type-I 15 ml moulded clear glass vial fitted with 20 mm bromo butyl rubber stopper and sealed with 20 mm pink flip off aluminium seal.

9. REGISTRATION NUMBER/REFERENCE NUMBER

AURO CEFOTAXIME 250 mg: 42/20.1.1/0601.

AURO CEFOTAXIME 500 mg: 42/20.1.1/0602.

AURO CEFOTAXIME 1000 mg: 42/20.1.1/0603.

AURO CEFOTAXIME 2000 mg: 42/20.1.1/0604.

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Aurogen South Africa (Pty) Ltd

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11. DATE OF PUBLICATION

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