

APPROVED PATIENT INFORMATION LEAFLET

SCHEDULLING STATUS: **S4**

AURO CEFEPIME INJECTION 500 mg (Powder for injection)

AURO CEFEPIME INJECTION 1000 mg (Powder for injection)

AURO CEFEPIME INJECTION 2000 mg (Powder for injection)

Cefepime dihydrochloride monohydrate

Read all of this leaflet carefully before you are given AURO CEFEPIME INJECTION

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **AURO CEFEPIME INJECTION** 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.

1. WHAT AURO CEFEPIME INJECTION CONTAINS

The active substance is cefepime.

AURO CEFEPIME INJECTION 500 mg:

Each vial contains cefepime dihydrochloride monohydrate equivalent to 500 mg cefepime.

AURO CEFEPIME INJECTION 1000 mg:

Each vial contains cefepime dihydrochloride monohydrate equivalent to 1000 mg cefepime.

AURO CEFEPIME INJECTION 2000 mg:

Each vial contains cefepime dihydrochloride monohydrate equivalent to 2000 mg cefepime.

The other ingredient contained in the **AURO CEFEPIME INJECTION** vials is L-arginine.

2. WHAT AURO CEFEPIME INJECTION IS USED FOR

Cefepime is an antibiotic belonging to the cephalosporin class. Antibiotics are used to kill the bacteria that cause infections. **AURO CEFEPIME INJECTION** is used to treat many kinds of bacterial infections, including infections of the chest, urinary systems, abdomen, gall bladder and skin.

3. BEFORE YOU ARE ADMINISTERED AURO CEFEPIME INJECTION

You should not be administered AURO CEFEPIME INJECTION:

- If you have ever had an unusual or allergic reaction to cefepime, to any other cephalosporin antibiotic, to a penicillin antibiotic, or to L-arginine.
- If you are pregnant or breast-feeding.

Tell your doctor or healthcare professional before being given the injection if:

- Tell your doctor if you have previously experienced an allergic reaction, particularly to medicines. If you experience any allergic symptoms while you are receiving **AURO CEFEPIME INJECTION**, stop using **AURO CEFEPIME INJECTION** and contact your doctor right away. Get emergency help if you have any of these signs of a serious allergic reaction: hives; difficulty breathing; swelling of your face, lips, tongue or throat.
- Tell your doctor if you have kidney disease.
- This medication may cause a severe intestinal condition called pseudomembranous colitis. Contact your doctor right away if stomach pain or cramps, severe or watery diarrhoea, or bloody stools occur.
- Use of **AURO CEFEPIME INJECTION** may result in an infection that occurs while you are being treated for an infection. Tell your doctor if signs of a second infection occur. Your doctor may need to change your treatment.
- **AURO CEFEPIME INJECTION** may interfere with urine glucose tests, possibly causing false positive test results. If you have diabetes and regularly check your urine for sugar, make sure all your doctors know you are using **AURO CEFEPIME INJECTION**.
- Kidney function declines as you grow older. This medication is removed by the kidneys. Therefore, elderly people may be at greater risk for side-effects while using **AURO CEFEPIME INJECTION**.

Pregnancy and Breast-feeding:

The safety of **AURO CEFEPIME INJECTION** in pregnancy and breast-feeding has not been established. Tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. If you become pregnant while taking **AURO CEFEPIME INJECTION**, call your doctor.

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 AURO CEFEPIME INJECTION:

Some medicines may interact with cefepime.

Tell your doctor if you are taking aminoglycosides (e.g gentamycin) or diuretics/water pills (e.g. furosemide) because the risk of toxic effects on the kidneys may be increased.

Before taking **AURO CEFEPIME INJECTION**, tell your doctor if you are using any other injected medicines such as:

- Metronidazole
- Vancomycin
- Gentamycin or tobramycin
- Aminophylline

Always tell your healthcare professional if you are taking any other medicine.

(This includes complementary or traditional medicines.)

4. HOW TO USE AURO CEFEPIME INJECTION

- **AURO CEFEPIME INJECTION** is usually given as an injection at your doctor's office, hospital, or clinic. The medication is given by injection into a muscle or vein as directed by your doctor.
- If you will be using **AURO CEFEPIME INJECTION** at home, a healthcare provider will teach you how to use it. Be sure you understand how to use **AURO CEFEPIME INJECTION**. Follow the procedures you are taught when you use a dose. Contact your healthcare provider if you have any questions.
- Before you administer **AURO CEFEPIME INJECTION**, look at the solution closely. It should be clear and free of floating material or particles.
- Keep this product, as well as syringes and needles, out of the reach of children and pets. Ask your healthcare provider how to dispose of these materials after use.
- Your dosage will depend on the type and severity of your infection.
- Your doctor will decide on the dose and length of time that you will receive **AURO CEFEPIME INJECTION**.
- For infants and children, the dose is based on body weight.
- Continue to use this medication until the full prescribed treatment period is finished, even if

symptoms disappear after a few days. Stopping the medication too early may result in a return of the infection.

- Tell your doctor if you suffer from kidney problems – your dosage may need to be reduced.

Always take **AURO CEFEPIME INJECTION** 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 CEFEPIME INJECTION** is too strong or too weak, talk to your doctor or pharmacist.

If you are administered more AURO CEFEPIME INJECTION than you should:

In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to use AURO CEFEPIME 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

AURO CEFEPIME INJECTION can have side-effects.

If you think that you are having an allergic (hypersensitivity) reaction to **AURO CEFEPIME INJECTION**, tell you doctor immediately or go to the emergency department at your nearest hospital.

Symptoms include:

- Skin rash, itching or hives
- Swelling of the face, lips, mouth or throat
- Difficulty breathing and swallowing
- Collapse

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

- Diarrhoea that is watery or bloody, severe stomach cramps
- Easy bruising or bleeding, unusual weakness
- Fever, chills, body aches, flu symptoms
- Fever, sore throat, and headache with a severe blistering, peeling, and red skin rash
- Seizure (black-out or convulsions)

- Yellowing eyes/skin
- Hallucinations
- Muscle twitching (myoclonus)

Other side-effects include: Fever; headache; dizziness; numbness, tingling; diarrhoea, feeling sick (nausea); vomiting; white patches or sores inside your mouth or on your lips (oral thrush); indigestion; taste disturbances; constipation; abdominal pain; vaginal itching or discharge; swelling, pain or tenderness at the injection site.

Tell your doctor if any of the above side-effects are severe, bothersome, do not go away or about any concerns you have while taking **AURO CEFEPIME INJECTION**.

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

6. STORING AND DISPOSING OF AURO CEFEPIME INJECTION

Store at or below 30 °C (room temperature). Keep the vial in the carton until required for use.

Once reconstituted with the recommended IV infusion fluids and IM diluents, the solution is to be used within 24 hours if stored below 25 °C (room temperature) or within 7 days if stored in the fridge (2 °C to 8 °C).

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

Store all medicines out of reach of children.

7. PRESENTATION OF AURO CEFEPIME INJECTION

AURO CEFEPIME INJECTION 500 mg:

20 ml Type-1 moulded clear colourless transparent glass vials fitted with 20 mm grey bromo butyl rubber stoppers and sealed with 20 mm Mapra beige colour aluminium flip off seal.

Pack size: Single vial packed in printed carton with a package insert.

AURO CEFEPIME INJECTION 1000 mg:

20 ml Type-1 moulded clear colourless transparent glass vials fitted with 20 mm grey bromo butyl rubber

stoppers and sealed with 20mm dark green colour aluminium flip off seal.

Pack size: Single vial packed in printed carton with a package insert.

AURO CEFEPIME INJECTION 2000 mg:

50 ml Type-1 moulded clear colourless transparent glass vials fitted with 32 mm grey bromo butyl rubber stoppers and sealed with 33 mm light orange colour aluminium flip off seal.

Pack size: Single vial packed in printed carton with a package insert.

8. IDENTIFICATION OF AURO-CEFEPIME INJECTION

White to pale yellow powder. When reconstituted, it is a clear colourless to pale yellow solution.

9. REGISTRATION NUMBERS/REFERENCE NUMBERS

AURO CEFEPIME INJECTION 500 mg: 41/20.1.1/0689

AURO CEFEPIME INJECTION 1 000 mg: 41/20.1.1/0690

AURO CEFEPIME INJECTION 2 000 mg: 41/20.1.1/0691

10. NAME AND ADDRESS OF REGISTRATION HOLDER

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11. DATE OF PUBLICATION

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