

## PATIENT INFORMATION LEAFLET

### CEFOZONE® (SULBACTAM & CEFOPERAZONE FOR INJECTION 1G)

**Read the entire leaflet carefully before you start using this medicine.**

Keep this leaflet. You may need to read it again. If you have any further questions, ask your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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#### IN THIS LEAFLET:

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#### 1. WHAT CEFOZONE IS AND WHAT IT IS USED FOR

The combination of Sulbactam and Cefoperazone is active against all organisms sensitive to cefoperazone. In addition, it demonstrates synergistic activity (up to 4-fold reduction in the minimum inhibitory concentrations for the combination versus those for each component) in a variety of organisms.

##### **Monotherapy**

It is indicated for the treatment of the following infections when caused by susceptible organisms:

- i. Respiratory tract infections (upper and lower)
- ii. Urinary tract infections (upper and lower)
- iii. Peritonitis, cholecystitis, cholangitis, and other intra-abdominal infections

- iv. Septicaemia
- v. Meningitis
- vi. Skin and soft tissue infections
- vii. Bone and joint infections
- viii. Pelvic inflammatory disease, endometritis, gonorrhoea, and other infections of the genital tract

##### **Combination Therapy**

Because of the broad spectrum of activity of Sulbactam/ Cefoperazone, most infections can be treated adequately with this antibiotic combination alone. However, CEFOZONE may also be used concomitantly with other antibiotics if such combinations are indicated. If an aminoglycoside is used, renal function should be monitored during the course of therapy.

#### 2. BEFORE YOU USE CEFOZONE

It is contraindicated in patients with a known allergy to penicillins, sulbactam, cefoperazone, or any of the cephalosporins.

#### WARNINGS AND PRECAUTIONS

Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients receiving beta-lactam or cephalosporin therapy. These reactions are more apt to occur in individuals with a history of hypersensitivity reactions to multiple allergens. If an allergic reaction occurs, the drug should be discontinued and the appropriate therapy instituted.

As with other antibiotics, overgrowth of non-susceptible organisms may occur during the prolonged use of CEFOZONE. It has not been extensively studied in premature infants or neonates. Therefore, in treating premature infants and neonates, the potential benefits and possible risks involved should be considered before instituting therapy.

### **Drug Interactions**

A reaction characterized by flushing, sweating, headache and tachycardia has been reported when alcohol was ingested during and as late as the fifth day after Cefoperazone administration. A similar reaction has been reported with certain other cephalosporins and patients should be cautioned concerning ingestion of alcoholic beverages in conjunction with administration of CEFOZONE. For patients requiring artificial feeding orally or parenterally, solutions containing ethanol should be avoided.

### **Hepatic Impairment**

In severe hepatic dysfunction, therapeutic concentrations of Cefoperazone are obtained in the bile and only a 2-to 4-fold increase in the half-life is seen. Dose modification may be necessary in case of severe biliary obstruction, severe hepatic disease or in case of renal dysfunction coexistent with either of those conditions.

### **Pregnancy**

There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

### **Lactation**

Caution should be exercised when CEFOZONE is administered to a nursing mother.

## **3. HOW TO TAKE CEFOZONE**

### **Adults**

The usual adult dose of the combination is 2 to 4 g/day (i.e, 1-2 g/day each of Cefoperazone and Sulbactam) given IV or IM in equally divided doses every 12 hours.

In severe or refractory infections the daily dosage may be increased to 8g (i.e, 4g/day each of Cefoperazone and Sulbactam) given IV in equally divided doses every 12 hours. The recommended maximum daily dosage of Sulbactam is 4g (8g of the combination).

### **Children**

The usual dosage in children is 40-80mg/kg/day (20 to 40 mg/kg/day each of Cefoperazone and Sulbactam) every six to twelve hours. In serious or refractory infections, these dosages may be increased up to 240mg/kg/day (160 mg/kg/day cefoperazone activity). Doses should be administered in two to four equally divided doses.

### **Intravenous Administration**

#### **Reconstitution**

For intravenous infusion, each vial of CEFOZONE should be reconstituted with the appropriate amount of 5% Dextrose, 0.9% Sodium Chloride Injection or Sterile Water for Injection, then further diluted to 20 mL with the same solution, and followed by administration over 15 to 60 minutes. Lactated Ringer's Solution is a suitable vehicle for intravenous infusion, but it is not, however, for initial reconstitution.

For intravenous injection, each vial should be reconstituted as above and administered over a minimum of 3 minutes.

## **4. POSSIBLE SIDE-EFFECTS**

CEFOZONE is generally well-tolerated. Majority of adverse events are of mild or moderate severity and are tolerated with continued treatment. The most frequent side effects observed with CEFOZONE have been gastrointestinal. Others include dermatologic reactions, headache, injection pain, chills, and

anaphylactic reactions.

## 5. HOW TO STORE CEFOZONE

### Keep out of the reach and sight of children.

Do not use CEFOZONE after the expiry date which is stated on the carton and on the vial label. The expiry date refers to the last day of that month.

Do not store above 25°C. Do not refrigerate or freeze.

### Reconstituted Solution

Reconstituted solution is stable for 7 days at 2-8°C and for 24 hours at 8-25°C.

For single use only, Discard any unused contents.

After reconstitution, the solution should be used immediately.

Do not use CEFOZONE if you notice signs of deterioration.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

## 6. FURTHER INFORMATION

### What CEFOZONE contains

- The active substance is Sulbactam and Cefoperazone

Each vial of CEFOZONE contains total 1g of Sulbactam and Cefoperazone

Also available in strengths of 1.5g and 2g

### What CEFOZONE looks like and contents of the pack

CEFOZONE is a dry powder for solution for injection.

It is supplied in a Glass vial with diluent in a carton

### Manufactured By:

TAJ PHARMACEUTICALS Ltd.  
Mumbai, INDIA

### Marketed By:

TAJ PHARMA INDIA LTD.  
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