

# Force™

Cefpirome

## COMPOSITION

**Force™** (Cefpirome) 1 gm IV injection: Each vial contains sterile powder mixture of Cefpirome Sulphate INN (equivalent to 1 gm of Cefpirome) and anhydrous Sodium Carbonate BP.

## INDICATION

1. Severe infections, such as septicemia, bacteremia and infections in immunosuppressed neutropenic patients with hematological malignancies
2. Lower respiratory infections including pneumonia
3. Severe urinary tract infections including pyelonephritis
4. Skin and soft tissue infections
5. Bone and joint infections
6. Infections in immunocompromised patients
7. Other infections

## DOSAGE AND ADMINISTRATION

**Force™** (Cefpirome) is administered only through the parenteral route. The dosage is dependent upon the severity and site of infection, the susceptibility of the infecting microorganisms and age, weight and renal function of the patient. The drug is administered through intravenous injection or infusion. The following dosages are recommended for moderate to severe infections in adult patients with normal renal function:

Indication	Unit dose (g)	Dosage interval (hours)	Total daily dose (g)
Complicated upper & lower urinary tract infections	1	12	2
Skin & soft tissue infections	1	12	2
Lower respiratory tract infections	1 to 2	12	2 to 4
Bacteraemia / septicaemia and severe infections	2	12	4
Infections in neutropenic patients	2	12	4

Dose reduction is necessary in patients with markedly reduced renal function. After an initial dose of 0.5 -2g to establish a high serum concentration, the dose should be reduced by 50% for clearances of 49-21 ml.min<sup>-1</sup> or 75% for clearances of 20 ml.min<sup>-1</sup>. In end-stage renal disease, a supplementary dose equal to 50% of the recommended daily dose should be administered after each hemodialysis treatment.

### Duration of treatment

The duration of treatment depends on the patient's clinical and bacteriological response.

### Route of administration

Intravenous route only.

## CONTRAINDICATION

Cefpirome is contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

## Adverse reactions

Cefpirome is generally well tolerated. There are no predictable life threatening effects of Cefpirome. Adverse gastrointestinal reactions include diarrhea, nausea,

vomiting, pseudomembraneous colitis, abdominal pain and have been noted 3.86% of the patients. Superficial phlebitis, thrombophlebitis and infection site reaction have been reported in 2.31% of patients receiving intravenous Cefpirome.

### The elderly

There are no special precautions for its use in the elderly provided dosage is adjusted accordingly to renal function.

## PREGNANCY AND LACTATION

The safety of Cefpirome has not been established in pregnancy and as with all agents it should be administered with caution, especially during the early months of pregnancy. As Cefpirome is excreted in human breast milk, either Cefpirome treatment should be discontinued or breast feeding ceased.

### Acute Over Dosage

No cases of over dosage are known. However, general supportive care with monitoring of renal, hematological and hepatic function and coagulation status is recommended.

### Drug Interactions

Drug interactions have not been observed with Cefpirome.

### Reconstitution procedure

"It is highly recommended to use the reconstituted solution immediately. During reconstitution the following procedure to be recommended and after reconstitution use within specified time line maintaining storage condition.

Step 1: Add recommended volume of solvent slowly. Remove the syringe needle.

Step 2: Gently shake the vial to dissolve the powder. Carbon dioxide is released & a clear solution will be obtained.

Step 3: Now insert the needle in the free space of the reconstituted vial & withdraw the pressurized air from the free space.

Step 4: Finally withdraw the solution from the vial by syringe."

## STORAGE CONDITION

**Force™** (Cefpirome) vial should be stored below 25°C, protected from light and moisture. Reconstituted solution can be stored for up to 6 hours at room temperature and 24 hours in refrigerator (at 2-8° C) when prepared in water for injection BP.

## HOW SUPPLIED

**Force™** 1 gm IV injection : Each pack contains 1 vial of Cefpirome 1gm as Cefpirome sulphate INN accompanied by a solvent ampoule of 10 ml water for injection BP. It also contains a complementary pouch comprised of disposable syringe (10 ml), butterfly needle, alcohol pad and first aid bandage.

Manufactured by:



TM-Trade Mark