

SAAFBACTUM

FOR IM/IV Injection
(Cefoperazone + Sulbactam)

سیف بیگٹم
(سیفوپیرازون + سلیبیکٹم)

Read all of this leaflet carefully before you start using this medicine because it contains important information for you. This medicine has been prescribed for you only. Do not pass it on to others, it may harm them even if their signs of illness are same as yours. For further instruction concern your doctor or pharmacist.

COMPOSITION:

Each Vial Contains:

Cefoperazone Sodium USP eq. to cefoperazone 500mg

Sulbactam Sodium USP eq. to sulbactam 500mg

Each Vial Contains:

Cefoperazone Sodium USP eq. to cefoperazone 1g

Sulbactam Sodium USP eq. to sulbactam 1g

Product complies Astellas Specs:

CLINICAL PHARMACOLOGY:

SAAFBACTUM a combination of Cefoperazone, a third generation of cephalosporin and sulbactam, B-lactamase inhibitor. Cefoperazone is a bactericidal agent, with broad spectrum of activity against most of the gram positive & gram negative pathogens. It also shows a good activity against the difficult to treat pathogens such as *Bacteroides fragilis*, *Clostridium difficile* and *Pseudomonas*, Sulbactam is B-lactamase inhibitor, which confers the following advantages:

- It inhibits B-lactamase produced by bacteria & protects Cefoperazone.
- Enhances the bactericidal activity by a synergistic action with Cefoperazone.
- Decreases the MIC values of organisms susceptible to Cefoperazone due to increased affinity to PBPs.
- A Cefoperazone resistant bacterium become susceptible by the addition of Sulbactam. Thus,

SAAFBACTUM is a unique combination with extensive spectrum of activity.

INDICATIONS:

- Respiratory tract infections (upper & lower)
- Urinary tract infections (upper & lower)
- Intra-abdominal infection, peritonitis, cholecystitis etc.
- Septicemia
- Infection in burn & wounds
- Skin & soft tissue infections
- Pelvic inflammatory disease, endometritis, gonorrhoea, other infection of genital tract
- Infections in immunocompromised patients
- Febrile neutropenic patients

For Prophylaxis:

- Laparoscopic surgery
- Cholecystectomy & other colorectal surgery.
- Plastic surgery
- Multiple fractures & complicated orthopaedic surgery

ADVERSE EFFECTS:

Generally **SAAFBACTUM** is well tolerated. However, mild and transient side effects such as: Hypersensitivity reactions, gastrointestinal effects diarrhoea, vomiting & nausea may be seen. Incidence of super infection is also observed as with other cephalosporins.

PRECAUTIONS & WARNING:

Hypersensitivity or allergy to penicillin Patients with renal/hepatic dysfunction. Renal & hematological status should be monitored, especially during prolonged & high dose therapy.

DOSAGE & ADMINISTRATION:

SAAFBACTUM is available as a dry powder for reconstitution. Sterile water for injection should be used for reconstitution.

Adults:

The usual dosag of **SAAFBACTUM** is 2-4g/day (i.e 1-2g/day of Cefoperazone activity), given IM/I.V in equally divided dose every 12 hours. The initial dose preferable, should be 2gm followed by 1 gm b.i.d in severe or refractory infections; the daily dosage may be increased to 8gm.

Children:

The usual dose in children is 40-80mg/kg/day (i.e. 20-40mg/kg/day Cefoperazone activity) in 2-4 equally divided doses. In serious infections, these dosages may be increased to 60mg/kg/day in 2-4 equally divided doses.

I.V Dose:

For intermittent infusion, each vial should be reconstituted with the appropriate amount of 5% dextrose in water, 0.9% sodium chloride injection, or sterile water for injection & then diluted to 20ml with the same solution followed by administration over 15-60 mins. For I.V injection, each vial should be reconstituted as above and administered over a minimum of 3 minutes.

I.M Dose:

Sterile water for injection should be used for reconstitution. For a concentration of Cefoperazone of 250mg/ml, a two step dilution is required using sterile water followed by Lignocaine solution.

STORAGE:

Store below 25°C
Protect from heat,
light and moisture.

PRESENTATION:

SAAFBACTUM 1g IM/IV Injection is available 1 Vial of Dry Substance
+1 Ampoule of 5ml Water for Injection

SAAFBACTUM 2g IM/IV Injection is available 1 Vial of Dry Substance
+1 Ampoule of 10ml Water for Injection

Marketed by: **ATHIX**
Pvt Ltd

Manufactured by:
Astellas Pharmaceuticals (Pvt.) Ltd.
15-C, Industrial Estate, Hayatabad,
Peshawar.

Manufactured for:
Winlet Pharmaceuticals (Pvt.) Ltd.
30-Km, Lahore Sargodha Road,
Sargodha.