POSOLOGY AND METHOD OF ADMINISTRATION.[1]

ADULTS:

Usual Dose: 2g - 4g given in 2 equal doses every 12 hours.
Severe Infections: Maximum dose 8g.
If more antibiotic is required, additional cefoperazone may be given separately.

CHILDREN:

Usual Dose: 40 - 80mg/kg/day given in equally divided doses every 6 to 12 hours.
Severe Infections: Maximum dose 160mg/kg/day.

INTRAVENOUS ADMINISTRATION (IV):

For intermittent intravenous infusion, each vial of Cefoperazone / Sulbactam should be reconstituted with a 6.7ml volume of diluent of 5% Dextrose in water or 0.9% Sodium chloride injection or Sterile water for injection and then diluted to 20 ml with the same solution followed by administration over 15 to 60 minutes. Lactated Ringer's solution is a suitable vehicle for intravenous infusion, however, not for initial reconstitution. 6.7ml of water for injections should be used and diluted with lactated Ringer's solution. **For intravenous injection**, each vial should be reconstituted as described above and to be administered over a minimum of 3 minutes.

INTRAMUSCULAR ADMINISTRATION (IM):

Lidocaine HCl 2% is a suitable vehicle for intramuscular administration, however, not for initial reconstitution.

SULCEF®
Cefoperazone/Sulbactam

SYNERGY IN TREATING BACTERIAL INFECTIONS

- **Twice** Daily.[1]
- **High efficacy** in severe infections.[1,2,3]
- **Low frequency** of adverse effects.[3]
- Still strong after **30 years of use.**
- Cost **effective.**
- Proven quality with **EU GMP certification**.[4]

Name of the Medicinal Product: Sulcef®. **Qualitative and Quantitative Composition:** Cefoperazone/sulbactam 1g/1g. **Pharmaceutical form:** Powder for Solution for Injection/Infusion. **Therapeutic indications:** Sulbactam/cefoperazone monotherapy is indicated for the treatment of the following infections when caused by susceptible organisms: Respiratory tract infections (upper and lower). Urinary tract infections (upper and lower). Peritonitis, cholecystitis, cholangitis, and other intra-abdominal infections. Septicaemia. Meningitis. Skin and soft tissue infections. Bone and joint infections. Pelvic inflammatory disease, endometritis, gonorrhoea, and other infections of the genital tract. **Posology and method of administration: Posology: Administration in adults:** Daily dosage recommendations for sulbactam/cefoperazone in adults are 2.0–4.0 g administered every 12 hours in equally divided doses. In severe or refractory to the treatment infections, the daily dose of sulbactam/cefoperazone may be increased up to 8g from the 1:1 ratio (i.e., cefoperazone activity-4g). Patients receiving the 1:1 ratio may require additional cefoperazone, administered separately. Daily dose should be administered every 12 hours in equally divided doses. The recommended maximum daily dosage of sulbactam is 4g. **Paediatric population:** Daily dosage recommendations for sulbactam/cefoperazone in children are 40–80 mg/kg/day every 6 to 12 hours, in equally divided doses. In serious or refractory to the treatment infections, these doses may be increased up to 160 mg/kg/day from the ratio 1:1 (i.e., cefoperazone activity - 160 mg/kg/day). Daily dose should be administered in two to four equally divided doses. Neonates: For neonates in the first week of life, the drug should be given every 12 hours. The maximum daily dosage of sulbactam in children should not exceed 80 mg/kg/day. **Method of administration: Intravenous Administration:** For intermittent intravenous infusion, each vial of sulbactam/cefoperazone should be reconstituted with the appropriate amount of 5% Dextrose in water, 0.9% Sodium chloride injection or Sterile water for injection and then diluted to 20 ml with the same solution followed by administration over 15 to 60 minutes. Lactated Ringer's solution is a suitable vehicle for intravenous infusion, however, not for initial reconstitution. For intravenous injection, each vial should be reconstituted as described above and to be administered over a minimum of 3 minutes. **Intramuscular Administration:** Lidocaine HCl 2% is a suitable vehicle for intramuscular administration, however, not for initial reconstitution. **Contraindications:** Sulbactam/cefoperazone is contraindicated in patients with established hypersensitivity to penicillins, sulbactam, cefoperazone or to other antibiotic from the cephalosporin-class or to any of the excipients. **Special warnings and precautions for use:** Hypersensitivity. Administration in hepatic impairment: Doses modification is required only in cases of severe biliary obstruction, severe hepatic disease or in cases of concomitant renal impairment and some of the above conditions. General principles: Cefoperazone/sulbactam should be discontinued if there is persistent bleeding and no alternative explanations are identified. Paediatric population: Administration in breast-fed children: Before prescribing therapy to pre-terms and newborns, the ratio benefits/risks should be assessed. This medicinal product contains 126 mg sodium per dose. To be taken into consideration by patients on a controlled sodium diet. **Interactions with other medicinal products and other forms of interaction:** Ethanol (Alcohol); Laboratory Test Interactions: A false-positive reaction for glucose in urine may occur with Benedict's or Fehling's solutions. **Pregnancy and Lactation:** This medicinal product should be used during pregnancy only if clearly needed. Caution should be exercised when sulbactam/cefoperazone is administered to a nursing woman. **Undesirable effects:** Common (1/100 to <1/10): Diarrhea/loose stools, positive direct Coombs' test, hypoprothrombinemia, transient eosinophilia, transient elevations of liver function enzymes values. **Date of revision of the text:** 11/2016. **MAH:** Medochemie Ltd.

REFERENCES:
1. Sulcef® Summary of product characteristics. **2.** Chia-Hung Chen Infection and Drug Resistance 2021:14 2251–2258. **3.** Chytra I, Anest. intenziv. Med. 2003, č6, s. 267-2772. **4.** H.S. Sader International Journal of Infectious Diseases 91 (2020) 32–37 **5.** EudraGMDP www.eudragmdp.ema.europa.eu.

employing 1880 profesionals **worldwide**

bringing 107 our therapies to **countries**

having 13 manufacturing **sites**

MEDOCHEMIE
1-10 Constantinoupoleos St., 3011 Limassol, Cyprus, Tel.: +357 25 867600 | office@medochemie.com
www.medochemie.com

ANALGESICS | ANTIDIABETICS | **ANTI-INFECTIVES** | CARDIOVASCULAR DRUGS | CNS DRUGS | DERMATOLOGICAL DRUGS | ENDOCRINE DRUGS | GASTROINTESTINAL DRUGS | RESPIRATORY / ANTI-ALLERGIC DRUGS | MISCELLANEA

code:

SULCEF®
Cefoperazone/Sulbactam

3rd Generation Cephalosporin
in combination with a **beta-lactamase inhibitor**

SYNERGY IN TREATING BACTERIAL INFECTIONS

- **High efficacy in severe infections**[1,2,3]
- **Among the most active compounds in vitro against Enterobacterales and P. aeruginosa**[4]

SULCEF®
Cefoperazone/Sulbactam

Sulcef is a combination of cefoperazone, a 3rd Generation cephalosporin and Sulbactam, a beta-lactamase inhibitor.[1]

THERAPEUTIC INDICATIONS[1]

- **Respiratory tract infections** (upper and lower)
- **Urinary tract infections** (upper and lower)
- **Peritonitis, cholecystitis, cholangitis and other intra-abdominal infections**
- **Septicaemia**
- **Meningitis**
- **Skin and soft tissue infections**
- **Bone and joint infections**
- **Pelvic inflammatory disease, endometritis, gonorrhoea and other infections of the genital tract**

SYNERGY IN TREATING BACTERIAL INFECTIONS

In adult patients with HAP/VAP,
Cefoperazone / Sulbactam 4g every 12 hours **is as effective as** **Piperacillin / Tazobactam** 4.5g every 8 hours.[2]

OVERALL Clinical Cure Rate

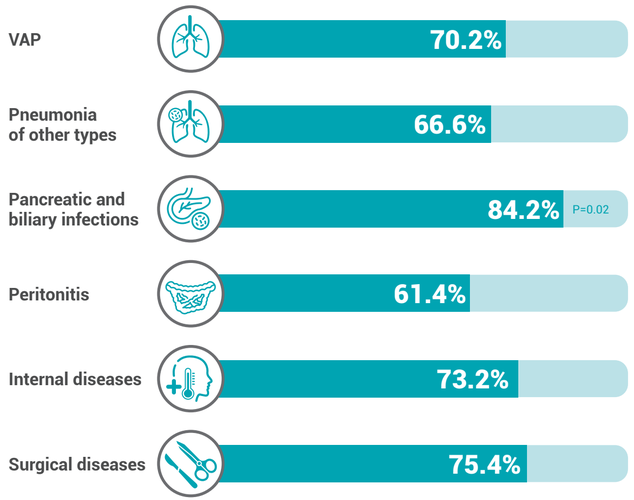
HAP Clinical Outcome

VAP Clinical Outcome

This study was based on **retrospective analyses**, using clinical information extracted from **BATTLE study** which evaluated the clinical efficacy of **Cefoperazon / Sulbactam** or **Piperacillin / Tazobactam** for the treatment of **HAP** or **VAP**.[2]

In Severe Intensive Care infections
Cefoperazone / Sulbactam showed **high efficacy with low frequency** of adverse effects..[3]

CLINICAL SUCCESS



This study was **multicenter, prospective, observational** evaluating efficacy and safety of different dosing regimens of **Cefoperazone / Sulbactam** in 198 patient with **severe intensive care infections**.[3]