

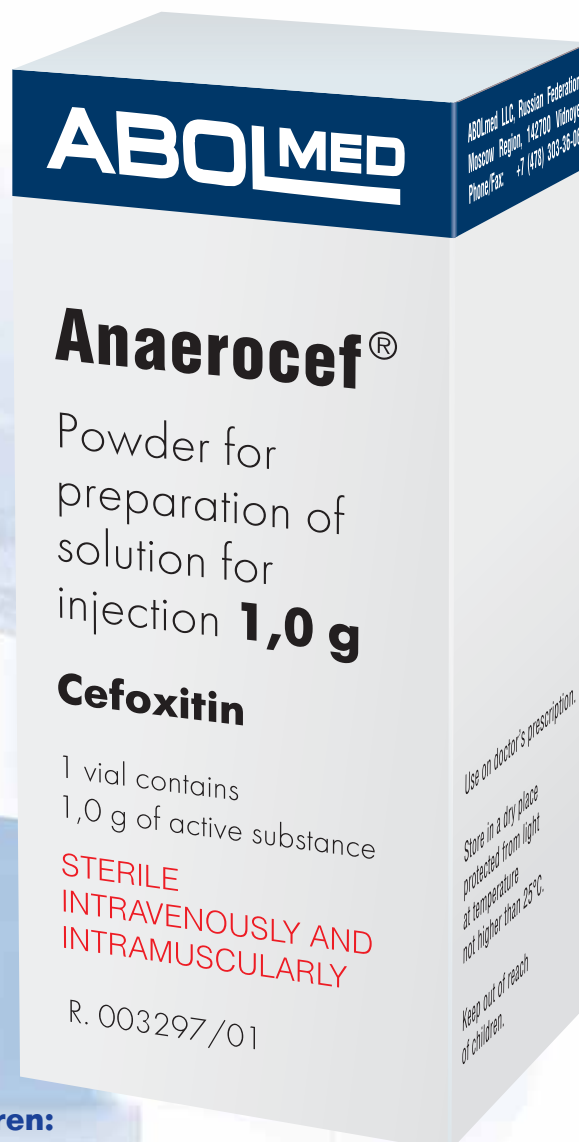
STANDARD OF SUCCESSFUL THERAPY OF MIXED AEROBIC-ANAEROBIC INFECTIONS

Anaerocef® (cefoxitin)

2nd generation cephalosporin with high activity against a wide range of Gram-positive and Gram-negative aerobes and anaerobes

First-choice antibiotic for treatment and prophylaxis of mixed infection in adults and children:

- lower respiratory tract infections, including aspiration pneumonia, pleural empyema and lung abscess
- urinary tract infections
- non-complicated and complicated intra-abdominal infections, including peritonitis and intra-abdominal abscesses
- bone and joint infections
- skin and skin structure infections (including post-operative wound infection)
- gynecological infections, including endometritis, pelvic cellulitis, and pelvic inflammatory disease (PID)
- septicemia
- antibiotic prophylaxis of post-operative surgical site infection in patients undergoing clean, clean-contaminated and contaminated surgical procedures



Anaerocef®

(cefoxitin)

DESCRIPTION

Anaerocef® (cefoxitin sodium) is a semi-synthetic, broad-spectrum group II cephalosporin for intramuscular or intravenous administration. It is unique derivative of cephamycin C, which is produced by *Streptomyces lactamdu-rans*.

CLINICAL PHARMACOLOGY

Clinical pharmacokinetic of **Anaerocef®** after IV or IM administration is described with linear model. Following an intravenous dose of 1 gram of **Anaerocef®**, serum concentrations were 110 mcg/mL at 5 minutes, declining to > 1 mcg/mL at 4 hours. **Anaerocef®** in detectable bactericidal concentration passes into most tissues, organs, and body fluids. The half-life after an intravenous administration is 41 to 59 minutes. Approximately 85 percent of **Anaerocef®** is excreted unchanged by the kidneys over a 6-hour period, resulting in high urinary concentrations.

SPECTRUM OF ACTIVITY

The bactericidal action of **Anaerocef®** results from inhibition of cell wall synthesis. **Anaerocef®** has activity against a wide range of Gram-positive and Gram-negative microorganisms and possesses a high degree of stability in the presence of beta-lactamases of Gram-negative aerobic and anaerobic bacteria.

Anaerocef® has been shown to be active against

Aerobic Gram-positive microorganisms

S. aureus (including penicillinase-producing strains), *S. epidermidis*, *Str. agalactiae*, *Str. pneumoniae*, *Str. pyogenes*

Aerobic Gram-negative microorganisms

E. coli, *H. influenzae*, *Klebsiella* spp. (including *K. pneumoniae*), *M. morgani*, *N. gonorrhoeae* (including penicillinase-producing strains), *P. mirabilis*, *P. vulgaris*, *Providencia* spp. (including *P. rettgeri*)

Anaerobic Gram-positive microorganisms

Clostridium spp., *C. perfringens*, *P. niger*, *Peptostreptococcus* spp.

Anaerobic Gram-negative microorganisms

B. distasonis, *B. fragilis*, *B. ovatus*, *B. thetaiotaomicron*, *Bacteroides* spp., *Eikenella corrodens*, *P. bivia*.

Anaerocef® is inactive against most strains of *P. aeruginosa* and enterococci. Most strains of *E. cloacae*, and staphylococci which are resistant to methicillin/oxacillin should be considered as resistant to **Anaerocef®**.

INDICATIONS AND USAGE

Anaerocef® is indicated for the treatment of moderate and serious infections caused by susceptible strains of the microorganisms in different localization. There are lower respiratory tract infections, including aspiration pneumonia, pleural empyema and lung abscesses, urinary tract infections, non-complicated and complicated intra-abdominal infections, including peritonitis and intra-abdominal abscesses, septicemia, bone and joint infections, skin and skin structure infections (including post-operative wound infection), gynecological infections, including endometritis, pelvic cellulitis, and pelvic inflammatory disease (PID). **Anaerocef®** has no activity against *C. trachomatis*. Therefore for the treatment of PID, when *C. trachomatis* is suspected pathogen, **Anaerocef®** should be combined with appropriate anti-chlamydial antimicrobials.

Many infections caused by aerobic and anaerobic gram-negative bacteria resistant to some cephalosporins respond to **Anaerocef®**.

Anaerocef® is indicated for the prophylaxis of post-operative surgical site infection in patients undergoing clean, clean-contaminated, contaminated surgical procedures, including gastrointestinal surgery, colorectal surgery, many traumatological procedures, vaginal hysterectomy, abdominal hysterectomy, cesarean section.

CONTRAINDICATIONS

Anaerocef® is contraindicated in patients who have shown hypersensitivity to cefoxitin and the cephalosporin group of antibiotics.

PRECAUTION

Pregnancy Category B. This drug should be used during pregnancy only if clearly needed. Caution should be exercised when **Anaerocef®** is administered to a nursing woman.

Drug Interactions

Increased nephrotoxicity has been reported following concomitant administration of cephalosporins and aminoglycoside antibiotics.

ADVERSE REACTIONS

Anaerocef® is generally well tolerated. The following reactions have been reported: thrombophlebitis at the site of IV injections, allergic reactions (rash, urticaria, flushing, pruritus, eosinophilia, fever, dyspnea, anaphylaxis, interstitial nephritis and angioedema); hypotension, diarrhea, pseudomembranous colitis, nausea and vomiting; possible exacerbation of myasthenia gravis; eosinophilia, leucopenia, anemia, thrombocytopenia and a change in Coombs' test; transient elevations in SGOT, SGPT, serum LDH, serum alkaline phosphatase and jaundice; elevations in serum creatinine and/or blood urea nitrogen. Serum samples from patients treated with **Anaerocef®** should not be analyzed for creatinine if withdrawn within 2 hours of drug administration, because high concentrations of **Anaerocef®** (>100 micrograms/mL) may produce false increases of modest degree in the levels of creatinine reported.

DOSAGE AND ADMINISTRATION

The usual adult dosage range is 1 gram to 2 grams every six to eight hours given IV or IM. Dosage and route of administration should be determined by susceptibility of the causative organisms, severity of infection, and the condition of the patient.

In newborns and premature children younger than 1 week old, the daily dose of 40-80 mg/kg is divided into 2 IV injections. **In newborns 2-4 week old**, the daily dose of 60-120 mg/kg is divided into 3 IV injections. The recommended dosage in pediatric patients over 1 months of age and older is 80 to 160 mg/kg of body weight per day divided into three to four equal doses. The higher dosages should be used for more severe or serious infections. The total daily dosage should not exceed 12 grams.

in adults, 2 grams administered intravenously just prior to surgery (approximately one-half hour before the initial incision) **for perioperative antibiotic prophylaxis**. If it is necessary, addition doses may be given every 6 hours after the first dose for no more than 24 hours. **In pediatric patients**, 30 to 40 mg/kg doses may be given IV at the times designated above. **In neonates**, the recommended dose is 30-40 mg/kg one-half hour before surgery; then 30-40 mg/kg repeated once after 8-12 hours. For patients undergoing cesarean section, either a single 2 grams dose administered intravenously as soon as the umbilical cord is clamped or (especially in high-risk patients) a 3-dose regimen consisting of 2 grams given intravenously as soon as the umbilical cord is clamped followed by 2 grams 4 and 8 hours after the initial dose is recommended.

Anaerocef® may be used in patients with reduced renal function with the following dosage interval adjustments (see the table). **In adults with renal insufficiency**, an initial loading dose of 1 gram to 2 grams may be given. **In patients undergoing hemodialysis**, the loading dose of 1 to 2 grams should be given after each hemodialysis, and the maintenance dose should be given as indicated in the table.

DOSAGES IN PATIENTS WITH RENAL IMPAIRMENT

| Cl _{creat} , mL/min | Serum creatinine, mg/100mL | Dose frequency, h |
|------------------------------|----------------------------|-------------------|
| >40 | >2 | 6-8 |
| 20-40 | 2-4 | 12 |
| 10-20 | 4-8 | 24 |
| 5-10 | >8 | 48* |

* - dose regimen in patients undergoing hemodialysis

HOW SUPPLIED

Anaerocef® is available in sterile dry powder form in vials containing sterile cefoxitin sodium equivalent to either 500 mg or 1 g of cefoxitin for intramuscular and intravenous administration (package of 50 vials).

Store for 2 years at or below a room temperature of 25°C (77°F).

Anaerocef® is manufactured by ABOLMED Ltd., Russia