

24 HOURS OF BACTERICIDAL ACTION AFTER ONE INJECTION

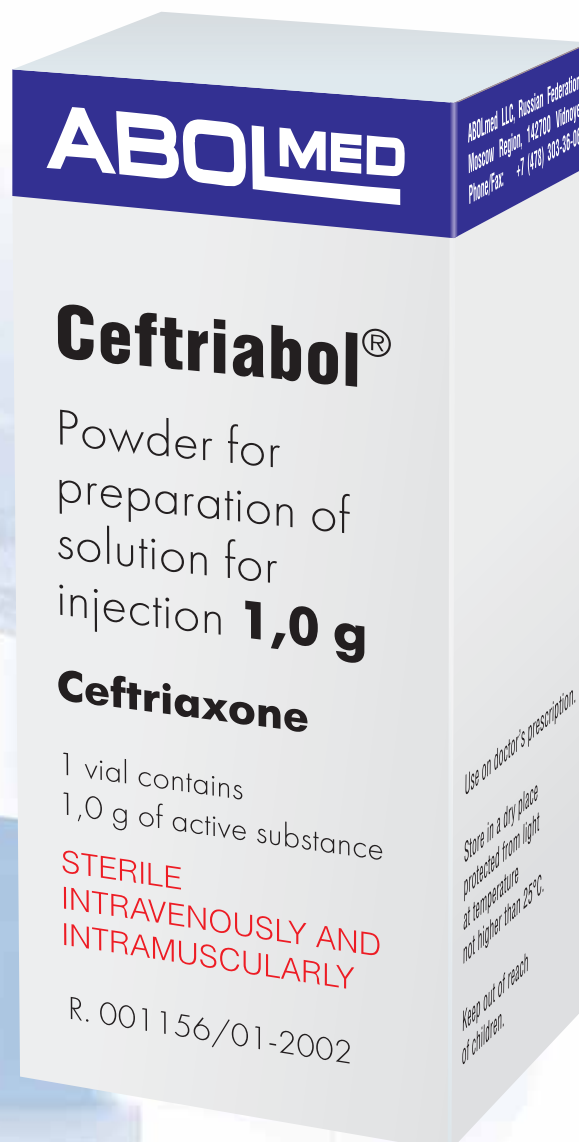
Ceftriabol®

(ceftriaxone)

3rd generation parenteral cephalosporin with high bactericidal effect against a wide range of Gram-positive and Gram-negative aerobes

Safe and effective management of different bacterial infections:

- bacterial meningitis
- infections of nose, ear and throat, including otitis media and sinusitis
- lower respiratory tract infections, including community-acquired and nosocomial pneumonia, lung abscesses, pleural empyema, exacerbation of chronic bronchitis, multiple bronchiectasis
- skin and skin structure infections
- complicated and uncomplicated urinary tract infections
- bone and joint infections, including septic arthritis and osteomyelitis
- uncomplicated gonorrhea, disseminated gonococcal infection
- syphilis
- pelvic inflammatory disease
- bacterial septicemia
- intra-abdominal infections, including peritonitis, cholecystitis, cholangitis
- Lyme disease (borreliosis)
- bacterial endocarditis
- severe enteric bacterial infection, including infections caused by *Salmonella spp.*, *Shigella spp.* or *E.coli*
- infections in immunocompromised patients, including febrile neutropenia
- commonly used antibiotic for perioperative antibiotic prophylaxis



ABOLMED
PHARMACEUTICAL COMPANY

Ceftriaabol®

(ceftriaxone)

DESCRIPTION

Ceftriaabol® (ceftriaxone sodium) is a sterile, semisynthetic, broad-spectrum 3rd generation cephalosporin antibiotic for intravenous or intramuscular administration. **Ceftriaabol®** possess high bactericidal effect against a wide spectrum of Gram-positive and Gram-negative aerobes as well as several anaerobes. Bactericidal action is mediated by inhibition of microbial cell wall components synthesis. **Ceftriaabol®** is highly resistant to the majority of beta-lactamases, both penicillinases and cephalosporinases of Gram-negative and Gram-positive bacteria.

SPECTRUM OF ACTIVITY

Ceftriaabol® is effective against the following microbes:

Gram-positive aerobes

S. aureus (except methicillin-resistant strains), *S. epidermidis* (except methicillin-resistant strains), *Str. pneumoniae*, *Str. pyogenes*, *Str. agalactiae*, *Str. viridans*, *Str. bovis*

Gram-negative aerobes

Aeromonas hydrophilia, *Alcaligenes* spp., *B. pertussis*, *Citrobacter* spp., *Enterobacter* spp. (several strains are resistant), *E. coli*, *H. ducreyi*, *H. influenzae* (including penicillinase-producing strains), *H. parainfluenzae*, *Klebsiella* spp. (including *K. pneumoniae*), *Moraxella* spp. (including *M. catarrhalis*), *M. morganii*, *N. gonorrhoeae* (including penicillinase-producing strains), *N. meningitidis*, *P. multocida*, *Plesiomonas shigelloides*, *P. mirabilis*, *P. vulgaris*, *Providencia* spp., *Salmonella* spp. (including *S. typhi*), *Serratia* spp. (including *S. marcescens*), *Shigella* spp., *Vibrio* spp. (including *Vibrio cholerae*), *Yersinia* spp. (including *Y. enterocolitica*)

Many strains cited above are multi-resistant to penicillins, cephalosporins of the 1st and 2nd generations (cefazolin, cefuroxime etc.) and aminoglycosides, but they are sensitive to **Ceftriaabol®**.

Anaerobes

Bacteroides spp., (including several strains of *B. fragilis* without beta-lactamases production), *Clostridium* spp. (except *C. difficile*), *Fusobacterium* spp. (except *F. mortiferum* and *F. varium*), *Peptococcus* spp., *Peptostreptococcus* spp.

Others

B. burgdorferi, *T. pallidum*, *Gardnerella* spp.

Resistant to **Ceftriaabol®**:

Enterococcus spp., methicillin-resistant staphylococci, *L. monocytogenes*, *B. anthracis*, *B. cereus*, the majority strains of *B. fragilis*, *C. difficile*, and the majority strains of *P. aeruginosa*.

PHARMACOKINETICS

After 1-2 h of IM and IV injection **Ceftriaabol®** maximally saturates serum and many organs, tissues and fluids. High (therapeutic) antibiotic concentrations are much more than inhibitory levels for pathogens could be determined in synovial, pleural and peritoneal fluids, in bones and joints, in skin and soft tissues, in kidneys, in organs of thoracic and abdominal cavities and in middle ear during 24 h after injection. Ceftriaxone penetrates the inflamed meninges in therapeutic concentrations. After a single IM or IV injections of therapeutic doses, high (>100 MIC of causative bacteria) bactericidal concentrations of ceftriaxone reaches in the middle ear fluid. A half-life of ceftriaxone in the middle ear fluid is **25 hours**. Concentrations in breast milk are low. **Ceftriaabol®** was completely absorbed following IM administration. Compared to other parenteral cephalosporines **Ceftriaabol®** has the longest half-life period (about 8h), what usually allows to inject it ONE time a day only. Ceftriaxone is reversibly bound to human plasma proteins, and the binding ranges from 85% to 95% at plasma concentrations. **Ceftriaabol®** has a double way of excretion. 50-60% of administered dose is excreted with urine unchanged within 24 h. 40-50% is excreted with bile.

INDICATIONS

Ceftriaabol® is indicated for the treatment of moderate and severe infections in different localizations: bacterial meningitis; infections of nose, ear and throat, including otitis media and sinusitis; lower respiratory tract infections, including community-acquired and nosocomial pneumonia, lung abscesses, pleural empyema, exacerbation of chronic bronchitis, multiple bronchiectasis; skin and skin structure infections, including erysipelas, cellulitis, diabetic foot infections; complicated and uncomplicated urinary tract infections; bone and joint infections, including septic arthritis, contiguous

osteomyelitis; uncomplicated gonorrhea, disseminated gonococcal infection; syphilis; pelvic inflammatory diseases; bacterial septicemia; complicated and uncomplicated intra-abdominal infections, including peritonitis, intra-abdominal abscesses, cholecystitis, cholangitis; Lyme disease (borreliosis); bacterial endocarditis; severe enteric bacterial infection, including infections caused by *Salmonella* spp., *Shigella* spp. or *E.coli*; infections in immunocompromised patients, including febrile neutropenia.

Surgical Prophylaxis: The preoperative administration of a single 1 gram dose of **Ceftriaabol®** may reduce the incidence of postoperative infections in patients undergoing surgical procedures classified as contaminated or potentially contaminated (e.g., vaginal or abdominal hysterectomy, biliary surgery, gastrointestinal and colorectal surgery) and in surgical patients for whom infection at the operative site would present serious risk (e.g., during coronary artery bypass surgery).

CONTRAINDICATIONS

Ceftriaabol® is contraindicated in patients who have shown immediate hypersensitivity reactions to ceftriaxone or the cephalosporin class of antibiotics.

PRECAUTIONS

Ceftriaabol® should be discontinued in patients who develop signs and symptoms suggestive of gallbladder disease and/or the abnormalities appear on sonography which may be misinterpreted as gallstones.

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

Ceftriaabol® should not be administered to hyperbilirubinemic neonates, especially prematures.

ADVERSE EFFECTS

Adverse effects are relatively rare. They are quickly disappear after the drug withdrawal. They are: allergic reactions, diarrhea, nausea, vomiting, dizziness, headache, stomatitis, glossitis, exanthema, allergic dermatitis, hyperemia, shiver, peripheral blood changes (eosinophilia, granulocytopenia, neutropenia, platelet decrease, haemolysis anemia), increase in hepatic enzymes activity, hypercreatininemia. Locally: infiltrates in the site of injection (after IM injections), phlebitis (after IV injections).

DOSAGE AND ADMINISTRATION

Ceftriaabol® may be administered intravenously or intramuscularly.

Adults and children older than 12 years old: The usual adult daily dose is 1 to 2 grams given once a day (or in equally divided doses twice a day) depending on the type and severity of infection. In severe cases the dose may be increased, but the total daily dose should not exceed 4 grams. In cases of mixed-infection (peritonitis, PID), anti-anaerobic antibiotics (metronidazole) should be added.

For antibiotic therapy of uncomplicated gonococcal infections the recommended dose is 250 mg as a single IM injection. In cases of disseminated gonococcal infection, the usual adult daily dose is 1 g given IM or IV once a day during 7 days. For antibiotic therapy of syphilis, 1 g of **Ceftriaabol®** should be administered IM or IV once a day during 14 days.

For preoperative use (surgical prophylaxis), a single dose of 1 gram administered intravenously 30 min before surgery is recommended.

Pediatric patients: In children older than 4 weeks and up to 12 years old the daily dose is 50-75 mg/kg once a day. The total daily doses should not exceed 2 grams. Doses higher than 50 mg/kg are administered as IV infusion. In newborns younger than 4 weeks irrelevantly of maturity the dose of 50 mg/kg is administered.

Ceftriaabol® can be widely used in patients with renal or liver deficiency without dosage correction.

HOW SUPPLIED

Ceftriaabol® is available in sterile dry powder form in vials containing sterile ceftriaxone sodium equivalent to 1 g of ceftriaxone for intramuscular and intravenous administration (package of 50 vials).

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

Ceftriaabol® is manufactured by ABOLMED Ltd., Russia