INSTRUCTIONS FOR MEDICAL USE

NOVAREXONE

Trade name: Novarexon

International Nonproprietary Name (INN): Ceftriaxone

Dosage form: Powder for solution for injection

Composition

Each 1.0 g vial of Novarexon contains:

Active substance: ceftriaxone sodium – 1200 mg (equivalent to 1000 mg of ceftriaxone).

Description

White to yellowish or yellow-orange crystalline powder in a clear glass vial.

Pharmacotherapeutic group

Systemic antimicrobial agents.

Systemic antibacterial agents.

Other beta-lactam antibacterial agents.

Third-generation cephalosporins.

Ceftriaxone.

ATC code: J01DD04

Pharmacological properties

Pharmacodynamics

Ceftriaxone is a semi-synthetic bactericidal antibiotic of the third-generation cephalosporins (beta-lactam group). Its mechanism of action is associated with inhibition of transpeptidase activity and disruption of peptidoglycan synthesis in the bacterial cell wall.

It has a broad spectrum of activity, including:

Aerobic Gram-positive microorganisms:

Staphylococcus aureus (including penicillinase-producing strains),

Staphylococcus epidermidis,

Streptococcus pneumoniae,

β-hemolytic group A streptococci (S. pyogenes),

Group B streptococci (S. agalactiae),

Streptococcus viridans,

Streptococcus bovis,

Non-enterococcal group D streptococci.

Gram-negative microorganisms:

Escherichia coli,

Haemophilus influenzae, H. parainfluenzae,

Klebsiella spp. (including K. pneumoniae),

Morganella morganii,

Proteus mirabilis, Proteus vulgaris,

Providencia spp.,

Salmonella spp. (including S. typhi),

Serratia spp. (including S. marcescens),

Shigella spp.,

Yersinia spp. (including Y. enterocolitica).

Microaerophiles: Treponema pallidum.

Aerobes: Neisseria gonorrhoeae (including penicillinase-producing strains),

Neisseria meningitidis,

Pseudomonas aeruginosa.

Obligate anaerobes: Bacteroides spp. (including some strains of B. fragilis),

Clostridium spp. (most C. difficile strains are resistant),

Peptococcus, Peptostreptococcus,

Fusobacterium spp. (including F. mortiferum and F. varium).

It is resistant to many beta-lactamases. Some acquired resistance is associated with beta-lactamase production.

Pharmacokinetics

The drug is not administered orally because it is rapidly degraded by gastric juice.

After intramuscular (IM) administration, it is rapidly and completely absorbed. Bioavailability is 100%. Protein binding is 85–95%.

Maximum plasma concentration (Cmax):

IM 1 g: about 80 mg/L after 1.5–3 hours

IV: 100–150 mg/L after 30 minutes

Therapeutic concentrations persist for more than 24 hours.

Half-life (T½): about 8 hours (may increase to 16 hours in neonates and elderly >75 years).

Excretion:

50–65% unchanged via kidneys within 48 hours

About 40% via bile

Crosses placenta; small amounts (3–4%) excreted in breast milk.

Indications

Treatment of infections caused by susceptible microorganisms:

Lower respiratory tract infections (pneumonia, bronchitis, lung abscess, pleural empyema)

ENT infections

Urinary tract and genital infections (pyelitis, cystitis, pyelonephritis, prostatitis, epididymitis)

Skin and soft tissue infections (including streptoderma)

Meningitis

Bone and joint infections

Peritonitis

Cholecystitis

Gastrointestinal infections

Uncomplicated gonorrhea and other STIs (including syphilis, chancroid)

Lyme disease

Typhoid fever

Salmonellosis and carrier state

Also used for prevention of postoperative infections.

Dosage and administration

Administered IM or IV.

For IM injection (to reduce pain), dilute:

0.5 g in 2 mL of 1% lidocaine

1 g in 3–5 mL of 1% lidocaine

Sterile water for injection may also be used.

For IV injection:

0.5 g in 5 mL sterile water

1 g in 10 mL sterile water

Adults and children >12 years:

1–2 g once daily or divided into two doses.

In severe cases: up to 4 g/day divided every 12 hours.

Prophylaxis: 1–2 g once, 30–90 minutes before surgery.

Neonates (up to 2 weeks): 20–50 mg/kg/day.

Children 2 weeks–12 years: 20–80 mg/kg/day.

Treatment duration: usually 4–14 days.

Adverse reactions

Allergic reactions (urticaria, pruritus, eosinophilia, anaphylaxis),

Gastrointestinal disturbances (nausea, vomiting, abdominal pain, pseudomembranous colitis),

Hematological changes (leukopenia, thrombocytopenia, hemolytic anemia),

Elevated liver enzymes, cholestatic jaundice,

Injection site reactions, phlebitis (IV use),

Rare: pancreatitis, arrhythmias.

Contraindications

Hypersensitivity to cephalosporins, penicillins, or lidocaine (for IM use).

Severe hepatic and renal failure.

History of gastrointestinal disease (especially ulcerative colitis, enteritis).

Pregnancy and lactation (unless benefit outweighs risk).

Drug interactions

Aminoglycosides – synergistic effect (monitor doses).

NSAIDs and antiplatelets – increased bleeding risk.

Loop diuretics – risk of nephrotoxicity.

Do not mix with calcium-containing solutions.

Special warnings

Monitor liver and kidney function in renal/hepatic impairment.

Possible biliary sludge on ultrasound.

Rare cases of pancreatitis.

Monitor prothrombin time in vitamin K deficiency.

Avoid mixing with calcium-containing IV solutions.

Overdose

Symptoms: dizziness, paresthesia, headache, seizures.

Treatment: symptomatic. Hemodialysis is ineffective.

Presentation

1.0 g in 10 mL clear colorless glass vials, sealed with rubber stoppers and aluminum/plastic caps.

1 or 20 vials per carton box with instructions for medical use.

Storage conditions

Store in a dry place, protected from light, at temperatures not exceeding 25°C.

Keep out of reach of children.

Shelf life 2 years.

Do not use after expiry date.

Dispensing conditions

Prescription only.

Manufacturer / Address for complaints in the Republic of Uzbekistan

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