Xoraxon

170225173014

Ceftriaxone sodium

COMPANY NAME: Medical Union Pharmaceuticals

Long-acting, broad-spectrum cephalosporin antibiotic for parenteral use

FORM: Vials containing dry substance equivalent to 500 mg and 1 g ceftriaxone

COMPOSITION: Ceftriaxone: (6R, 7R)-7-[(Z)-2-(2-amino-4-thiazolyl)-2-[methoxyimino] acetamido)-3-[(2, 5-dihydro-6-hydroxy-2-methyl-5-Oxo-as-triazin-3-yl)thio] methyl]-8-Oxo-5-thia-1-azabicyclo [4.2. 0] oct-2-ene-carboxylic acid in the form of the disodium salt.

Xoraxon contains approximately 83 mg (3.6 mEq) of sodium per gram of ceftriaxone.

Each Xoraxon 500 mg. vial for I.M. injection contains:
Active constituent: Ceftriaxone 0.5g (as sterile Ceftriaxone sodium 596,5 mg).
Diluent: 1% lidocaine hydrochloride injection.
Each 2 ml ampoule contains: Lidocaine hydrochloride 0.02 g

Each Xoraxon 500mg. vial for I.V. injection contains:
Active constituent: Ceftriaxone 0.5 g (as sterile Ceftriaxone sodium 596.5 mg).
Diluent: sterile water for injection, of volume = 5 ml.

Each Xoraxon 1g. Vial for I.M. injection contains:
Active constituent: Ceftriaxone 1 g (as sterile Ceftriaxone sodium 1193 mg).
Diluent: 1% lidocaine hydrochloride injection.
Each 4 ml ampoule contains: Lidocaine hydrochloride 0.04g

Each Xoraxon 1g Vial for I.V. injection contains:
Active constituent: Ceftriaxone 1 g (as sterile Ceftriaxone sodium 1193 mg).
Diluent: sterile water for injection, of volume = 10 ml.

PROPERTIES, EFFECTS Microbiology: The bactericidal effect of ceftriaxone results from inhibition of cell wall synthesis. Ceftriaxone exerts in vitro activity against a wide range of gram-negative and gram-positive microorganisms. Ceftriaxone is highly stable to most b-lactamases, both penicillinases and cephalosporinases, of gram-positive and gram-negative bacteria.

PHARMACOKINETICS: Ceftriaxone is characterized by unusually long elimination half-life of approximately eight hours in healthy adults. The area under the plasma concentration time curves after I.V., and I.M. administration is identical. This means that the bioavailability of ceftriaxone administrated I.M. is 100%. On intravenous administration, ceftriaxone diffuses rapidly into the interstitial fluid, where bactericidal concentrations against susceptible organisms are maintained for 24 hours.

Elimination: The elimination half-life in healthy adults is about eight hours. In infants aged less than eight days and in persons over 75 years of age, the average elimination half-life is about twice as long. In adults, 50-60% of ceftriaxone is excreted unchanged by the kidneys, while 40-50% is excreted unchanged in the bile. The intestinal flora transforms ceftriaxone into inactive metabolites. In neonates, renal elimination accounts for about 70% of the dose. In patients with renal impairment or hepatic dysfunction, the pharmacokinetics of ceftriaxone is only minimally altered and the elimination half-life is only slightly increased. If kidney function alone is impaired, biliary elimination of ceftriaxone is increased, if liver function alone is impaired, renal elimination is increased.

Protein binding: Ceftriaxone is reversibly bound to albumin, and the binding decreases with the increase in the concentration, e.g. from 95% binding at plasma concentrations of <100 mg/l to 85% binding at 300 mg/L. Owing to the lower albumin content, the proportion of free ceftriaxone in interstitial fluid is correspondingly higher than in plasma.

Penetration into the cerebrospinal fluid: Ceftriaxone penetrates the inflamed meninges of infants and children. The average extent of diffusion in the cerebrospinal fluid in bacterial meningitis is 17% of the plasma concentration, i.e. approximately four times that in aseptic meningitis. Ceftriaxone concentrations of >1.4 mg/l have been found in the CSF 24 hours after I.V. injection of Xoraxon in doses of 50-100 mg/kg. In adult meningitis patients, administration of 50 mg/kg leads within 2-24 hours to CSF concentrations several times higher than the minimum inhibitory concentrations required for most common causative organisms of meningitis.

INDICATIONS AND USAGE

Xoraxon is indicated for the treatment of the following infections when caused by susceptible organisms:

LOWER RESPIRATORY TRACT INFECTIONS: caused by Streptococcus pneumoniae, Staphylococcus aureus, Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella pneumoniae, Escherichia coli, Enterobacter aerogenes, Proteus mirabilis or Serratia marcescens.

ACUTE BACTERIAL OTITIS MEDIA: caused by Streptococcus pneumoniae, Haemophilus influenzae (including beta-lactamase producing strains) or Moraxella catarrhalis (including beta-lactamase producing strains).

SKIN AND SKIN STRUCTURE INFECTIONS: caused by Staphylococcus aureus, Staphylococcus epidermidis, Streptococcus pyogenes, Viridans group streptococci, Escherichia coli, Enterobacter cloacae, Klebsiella oxytoca, Klebsiella pneumoniae, Proteus mirabilis, Morganella morganii,1Pseudomonas aeruginosa, Serratia marcescens, Acinetobacter calcoaceticus, Bacteroides fragilis1or Peptostreptococcus species.

URINARY TRACT INFECTIONS: (complicated and uncomplicated) caused by Escherichia coli, Proteus mirabilis, Proteus vulgaris, Morganella morganii or Klebsiella pneumoniae.

UNCOMPLICATED GONORRHEA: (cervical/urethral and rectal) caused by Neissena gonorrhea, including both penicillinase- and nonpenicillinase-producing strains, and pharyngeal gonorrhea caused by nonpenicillinase-producing strains of Neisseria gonorrhea.

PELVIC INFLAMMATORY DISEASE: caused by Neisseria gonorrhea. Xoraxon, like other cephalosporin, has no activity against Chlamydia trachomatis. Therefore, when cephalosporin are used in the treatment of patients with pelvic inflammatory disease and Chlamydia trachomatis is one of the suspected pathogens, appropriate antichlamydial coverage should be added.

BACTERIAL SEPTICEMIA: caused by Staphylococcus aureus, Streptococcus pneumoniae, Escherichia coli, Haemophilus influenzae or Klebsiella pneumoniae.

BONE AND JOINT INFECTIONS: caused by Staphylococcus aureus, Streptococcus pneumoniae, Escherichia coli, Proteus mirabilis, Klebsiella pneumoniae or Enterobacter species.

INTRA-ABDOMINAL INFECTIONS: caused by Escherichia coli, Klebsiella pneumoniae, Bacteroides fragilis, Clostridium species (Note: most strains of Clostridium difficile are resistant) or Peptostreptococcus species.

MENINGITIS: caused by Haemophilus influenzae, Neisseria meningitides or Streptococcus pneumoniae. Xoraxon has also been used successfully in a limited number of cases of meningitis and shunt infection caused by Staphylococcus epidermidis * and Escherichia coli *.

* *Efficacy for this organism in this organ system was studied in fewer than ten infections.*

SURGICAL PROPHYLAXIS: The preoperative administration of a single 1gm. dose of Xoraxon may reduce the incidence of postoperative infections in patients undergoing surgical procedures classified as contaminated or potentially contaminated (eg, vaginal or abdominal hysterectomy or cholecystectomy for chronic calculus cholecystitis in high-risk patients, such as those over 70 years of age, with acute cholecystitis not requiring therapeutic antimicrobials, obstructive jaundice or common duct bile stones) and in surgical patients for whom infection at the operative site would present serious risk (e.g., during coronary artery bypass surgery). Although Xoraxon has been shown to have been as effective as cefazolin in the prevention of infection following coronary artery bypass surgery, no placebo-controlled trials have been conducted to evaluate any cephalosporin antibiotic in the prevention of infection following coronary artery bypass surgery.

When administered prior to surgical procedures for which it is indicated, a single 1 gm. dose of Xoraxon provides protection from most infections due to susceptible organisms throughout the course of the procedure.

CONTRAINDICATIONS: Xoraxon is contraindicated in patients with known hypersensitivity to ceftriaxone, other cephalosporins or to any of the excipients.

Previous immediate and /or severe hypersensitivity reaction to penicillin or to any other beta-lactam medicinal products.

Ceftriaxone must not be mixed or administered simultaneously with calcium containing solution or products, even via separate infusion lines, furthermore, calcium containing solution products must not be administered within 48 hours of the last Ceftriaxone administration, as a small Numberof cases of fatal cases in which a crystalline material of calcium-ceftriaxone precipitates in the lungs and kidneys.

Neonates (28 days) Hyperbilirubinaemia neonates, especially premature, should not be treated with ceftriaxone. In vitro studies have shown that ceftriaxone can displace bilirubin from its binding to serum albumin, leading to a possible risk of bilirubin encephalopathy in these patients.

Ceftriaxone is contraindicated in neonates if they require (or are expected to require) treatment with calcium-containing IV solutions, including continuous calcium-containing infusions such as parenteral nutrition because of the risk of precipitation of ceftriaxone-calcium (see CLINICAL PHARMACOLOGY, WARNINGS and DOSAGE AND ADMINISTRATION). A small number of cases of fatal outcomes in which a crystalline material was observed in the lungs and kidneys at autopsy have been reported in neonates receiving ceftriaxone and calcium-containing fluids. In some of these cases, the same intravenous infusion line was used for both ceftriaxone and calcium-containing fluids and in some a precipitate was observed in the intravenous infusion line. At least one fatality has been reported in a neonate in whom ceftriaxone and calcium-containing fluids were administered at different time points via different intravenous lines; no crystalline material was observed at autopsy in this neonate. There have been no similar reports in patients other than neonates.

WARNINGS:

Hypersensitivity:

BEFORE THERAPY WITH CEFTRIAXONE IS INSTITUTED, CAREFUL INQUIRY SHOULD BE MADE TO DETERMINE WHETHER THE PATIENT HAS HAD PREVIOUS HYPERSENSITIVITY REACTIONS TO CEPHALOSPORINS, PENICILLINS OR OTHER DRUGS.

THIS PRODUCT SHOULD BE GIVEN CAUTIOUSLY TO PENICILLIN-SENSITIVE PATIENTS. ANTIBIOTICS SHOULD BE ADMINISTERED WITH CAUTION TO ANY PATIENT WHO HAS DEMONSTRATED SOME FORM OF ALLERGY, PARTICULARLY TO DRUGS. SERIOUS ACUTE HYPERSENSITIVITY REACTIONS MAY REQUIRE THE USE OF SUBCUTANEOUS EPINEPHRINE AND OTHER EMERGENCY MEASURES.

Special caution is required to determine any of the other type of previous hypersensitivity reactions to penicillin or to other beta- lactam medicinal products because patients hypersensitive to these medicines may be hypersensitive to ceftriaxone as well (cross allergy).

As with other cephalosporin, anaphylactic reactions with fatal outcome have been reported, even if a patient is not known to be allergic or previously exposed.

Interaction with Calcium-Containing Products: Do not use diluents containing calcium, such as Ringer's solution or Hartmann's solution, to reconstitute Xoraxon vials or to further dilute a reconstituted vial for IV administration because a precipitate can form. Precipitation of ceftriaxone-calcium can also occur when Xoraxon is mixed with calcium-containing solutions in the same IV administration line. Xoraxon must not be administered simultaneously with calcium-containing IV solutions, including continuous calcium-containing infusions such as parenteral nutrition via a Y-site. However, in patients other than neonates, Xoraxon and calcium-containing solutions may be administered sequentially of one another if the infusion lines are thoroughly flushed between infusions with a compatible fluid. In vitro studies using adult and neonatal plasma from umbilical cord blood demonstrated that neonates have an increased risk of precipitation of ceftriaxone-calcium (see CLINICAL PHARMACOLOGY, CONTRAINDICATIONS and DOSAGE AND ADMINISTRATION).

Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including Xoraxon, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of C. Difficile. C. difficile produces toxins A and B which contribute to the development of CDAD. Hypertoxin producing strains of C. difficile cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibiotic use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents. If CDAD is suspected or confirmed, ongoing antibiotic use not directed against C. difficile may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of C. difficile, and surgical evaluation should be instituted as clinically indicated. Hemolytic Anemia An immune mediated hemolytic anemia has been observed in patients receiving cephalosporin class antibacterial including Xoraxon. Severe cases of hemolytic anemia, including fatalities, have been reported during treatment in both adults and children. If a patient develops anemia while on ceftriaxone, the diagnosis of a cephalosporin associated anemia should be considered and ceftriaxone stopped until the etiology is determined.

PRECAUTIONS:

General Prescribing Xoraxon in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient and increases the risk of the

not be necessary in patients with hepatic dysfunction; however, in patients with both hepatic dysfunction and significant renal disease, caution should be exercised and the Xoraxon dosage should not exceed 2 gm. daily. Alterations in prothrombin times have occurred rarely in patients treated with Xoraxon. Patients with impaired vitamin K synthesis or low vitamin K stores (e.g., chronic hepatic disease and malnutrition) may require monitoring of prothrombin time during Xoraxon treatment. Vitamin K administration (10 mg weekly) may be necessary if the prothrombin time is prolonged before or during therapy. Prolonged use of Xoraxon may result in overgrowth of nonsusceptible organisms. Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken.

Xoraxon should be prescribed with caution in individuals with a history of gastrointestinal disease, especially colitis. There have been reports of sonographic abnormalities in the gallbladder of patients treated with Ceftriaxone (Xoraxon); some of these patients also had symptoms of gallbladder disease. These abnormalities appear on sonography as an echo without acoustical shadowing suggesting sludge or as an echo with acoustical shadowing which may be misinterpreted as gallstones. The chemical nature of the sonographically detected material has been determined to be predominantly a ceftriaxone-calcium salt. The condition appears to be transient and reversible upon discontinuation of Ceftriaxone (Xoraxon) and institution of conservative management. Therefore, Xoraxon should be discontinued in patients who develop signs and symptoms suggestive of gallbladder disease and/or the sonographic findings described above. Cases of pancreatitis, possibly secondary to biliary obstruction, have been reported rarely in patients treated with Ceftriaxone (Xoraxon). Most patients presented with risk factors for biliary stasis and biliary sludge (preceding major therapy, severe illness, and total parenteral nutrition). A cofactor role of Ceftriaxone -related biliary precipitation cannot be ruled out.

Information for Patients should be counseled that antibacterial drugs including Xoraxon should only be used to treat bacterial infections. They do not treat viral infections (e.g., common cold). When Xoraxon is prescribed to treat a bacterial infection, patients should be told that although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may (1) decrease the effectiveness of the immediate treatment and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by Xoraxon or other antibacterial drugs in the future. Diarrhea is a common problem caused by antibiotics which usually ends when the antibiotic is discontinued. Sometimes after starting treatment with antibiotics, patients can develop watery and bloody stools (with or without stomach cramps and fever) even as late as two or more months after having taken the last dose of the antibiotic. If this occurs, patients should contact their physician as soon as possible.

Pregnancy Teratogenic Effects

No embryotoxicity or teratogenicity was demonstrated at a dose approximately 3times the human dose. This drug should be used during pregnancy only if clearly needed.

Nursing Mothers Low concentrations of ceftriaxone are excreted in human milk. Caution should be exercised when Xoraxon is administered to a nursing woman. Pediatric Use Safety and effectiveness of Xoraxon in neonates, infants and pediatric patients have been established for the dosages described in the DOSAGE AND ADMINISTRATION section. In vitro studies have shown that ceftriaxone, like some other cephalosporin, can displace bilirubin from serum albumin. Xoraxon should not be administered to hyperbilirubinaemia neonates, especially premature (see CONTRAINDICATIONS).Geriatric Use Of the total number of subjects in clinical studies of Ceftriaxone (Xoraxon), 32% were60 and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out. The pharmacokinetics of ceftriaxone were only minimally altered in geriatric patients compared to healthy adult subjects and dosage adjustments are not necessary for geriatric patients with ceftriaxone dosages up to 2 grams per day (see CLINICAL PHARMACOLOGY).

ADVERSE REACTIONS: Xoraxon is generally well tolerated. In clinical trials, the following adverse reactions, which were considered to be related to xoraxon therapy or of uncertain etiology, were observed:

LOCAL REACTIONS-pain, induration and tenderness was 1% overall. Phlebitis was reported in <1% after IV administration. The incidence of warmth, tightness or induration was 17% (3/17) after IM administration of 350mg/mL and 5%(1/20) after IM administration of 250 mg/mL.

HYPERSENSITIVITY-rash (1.7%). Less frequently reported (<1%) were pruritus, fever or chills.

HEMATOLOGIC-eosinophilia (6%), thrombocytosis (5.1%) and leukopenia (2.1%). Less frequently reported (<1%) were anemia, hemolytic anemia, neutropenia, lymphopenia, thrombocytopenia and prolongation of the prothrombin time.

GASTROINTESTINAL-diarrhea (2.7%). Less frequently reported (< 1%) were nausea or vomiting, and disguise. The onset of pseudomembranous colitis symptoms may occur during or after antibacterial treatment (see WARNINGS).

HEPATIC-elevations of SGOT (3.1%) or SGPT (3.3%). Less frequently reported (< 1%) were elevations of alkaline phosphatase and bilirubin.

RENAL-elevations of the BUN (1.2%). Less frequently reported (<1%) were elevations of creatinine and the presence of casts in the urine.

CENTRAL NERVOUS SYSTEM-headache or dizziness were reported occasionally (< 1%).

GENITOURINARY-moniliasis or vaginitis were reported occasionally (< 1%.).

MISCELLANEOUS-diaphoresis and flushing were reported occasionally(< 1%)

Other rarely observed adverse reactions (<1%) include abdominal pain, agranulocytosis, allergic pneumonitis, anaphylaxis, basophilia, biliary lithiasis, bronchospasm, colitis, dyspepsia, epistaxis, flatulence, gallbladder sludge, glycosuria, hematuria, jaundice, leukocytosis, lymphocytosis, monocytosis, nephrolithiasis, palpitations, a decrease in the prothrombin time, renal precipitations, seizures, and serum sickness.

POSTMARKETING EXPERIENCE: In addition to the adverse reactions reported during clinical trials, the following adverse experiences have been reported during clinical practice in patients treated with Ceftriaxone (Xoraxon). Data are generally insufficient to allow an estimate of incidence or to establish causation.

A small number of cases of fatal outcomes in which a crystalline material was observed in the lungs and kidneys at autopsy have been reported in neonates receiving Ceftriaxone (Xoraxon) and calcium-containing fluids. In some of these cases, the same intravenous infusion line was used for both Ceftriaxone (Xoraxon) and calcium-containing fluids and in some a precipitate was observed in the intravenous infusion line. At least one fatality has been reported in a neonate in whom Ceftriaxone (Xoraxon) and calcium-containing fluids were administered at different time points via different intravenous lines; no crystalline material was observed at autopsy in this neonate. There have been no similar reports in patients other than neonates.

GASTROINTESTINAL - stomatitis and glossitis.

GENITOURINARY - oliguria.

DERMATOLOGIC - exanthema, allergic dermatitis, urticaria, edema. As with many medications, isolated cases of severe cutaneous adverse reactions (erythema multiform, Stevens-Johnson syndrome or Lyell's syndrome/toxic epidermal necrosis) have been reported.

Cephalosporin Class Adverse Reactions In addition to the adverse reactions listed above which have been observed in patients treated with ceftriaxone, the following adverse reactions and altered laboratory test results have been reported for cephalosporin class antibiotics:

Adverse Reactions: Allergic reactions, drug fever, serum sickness-like reaction, renal dysfunction, toxic nephropathy, reversible hyperactivity, hypertonia, hepatic dysfunction including cholestasis, aplastic anemia, hemorrhage, and superinfection.

Altered Laboratory Tests: Positive direct Coombs' test, false-positive test for urinary glucose, and elevated LDH. Several cephalosporins have been implicated in triggering seizures, particularly in patients with renal impairment when the dosage was not reduced (see DOSAGE & ADMINISTRATION). If seizures associated with drug therapy occur, the drug should be discontinued. Anticonvulsant therapy can be given if clinically indicated.

OVERDOSAGE: In the case of overdosage, drug concentration would not be reduced by hemodialysis or peritoneal dialysis. There is no specific antidote. Treatment of overdosage should be symptomatic.

INTERACTIONS: No impairment of renal function has so far been observed after concurrent administration of large doses of (Xoraxon) and potent diuretics (e.g. Furosemide). There is no evidence that (Xoraxon) increases renal toxicity of aminoglycosides. No effect similar to that of disulfiram has been demonstrated after ingestion of alcohol subsequent to the administration of (Xoraxon). Ceftriaxone does not contain an N -methylthiotetrazole moiety associated with possible ethanol intolerance and bleeding problems of certain other cephalosporin. The elimination of (Xoraxon) is not altered by probenecid.

DOSAGE AND ADMINISTRATION: Xoraxon may be administered intravenously or intramuscularly.

PEDIATRIC PATIENTS

For the treatment of skin and skin structure infections, the recommended total daily dose is 50 to 75 mg/kg given once a day (or in equally divided doses twice a day). The total daily dose should not exceed 2 grams. For the treatment of acute bacterial otitis media, a single intramuscular dose of 50 mg/kg (not to exceed 1 gram) is recommended (see INDICATIONS AND USAGE). For the treatment of serious miscellaneous infections other than meningitis, the recommended total daily dose is 50 to 75 mg/kg, given in divided doses every 12 hours. The total daily dose should not exceed 2 grams.

In the treatment of meningitis, it is recommended that the initial therapeutic dose be 100 mg/kg (not to exceed 4 grams). Thereafter, a total daily dose of 100 mg/kg/day (not to exceed 4 grams daily) is recommended. The daily dose may be administered once a day (or in equally divided doses every 12 hours). The usual duration of therapy is 7 to 14 days.

ADULTS: 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. For infections caused by Staphylococcus aureus (MSSA), the recommended daily dose is 2 to 4 grams, in order to achieve >90% target attainment. The total daily dose should not exceed 4 grams. If Chlamydia trachomatis is a suspected pathogen, appropriate antichlamydial coverage should be added, because ceftriaxone sodium has no activity against this organism. For the treatment of uncomplicated gonococcal infections, a single intramuscular dose of 250 mg is recommended. For preoperative use (surgical prophylaxis): a single dose of 1 gram administered intravenously ½ to 2 hours before surgery is recommended. Generally, Xoraxon therapy should be continued for at least 2 days after the signs and symptoms of infection have disappeared. The usual duration of therapy is 4 to 14 days; in complicated infections, longer therapy may be required. When treating infections caused by Streptococcus pyogenes, therapy should be continued for at least 10 days. No dosage adjustment is necessary for patients with impairment of renal or hepatic function.

DIRECTIONS FOR USE:

- Intramuscular Administration:

Reconstitute Xoraxon powder with the appropriate diluent (see COMPATIBILITY AND STABILITY). Inject diluent into vial, shake vial thoroughly to form solution. Withdraw entire contents of vial into syringe to equal total labeled dose.

After reconstitution, each 1 mL of solution contains approximately 250 mg or 350 mg equivalent of ceftriaxone according to the amount of diluent indicated below. If required, more dilute solutions could be utilized.

As with all intramuscular preparations, Xoraxon should be injected well within the body of a relatively large muscle; aspiration helps to avoid unintentional injection into a blood vessel.

Vial Dosage Size	Amount of Diluent to be added	
	250 g/mL	350 g/mL
500 mg	1.8 mL	1 mL
1 gm	3.6 mL	2.1 mL

- Intravenous Administration:

Xoraxon should be administered intravenously by infusion over a period of 30 minutes. Concentrations between 10 mg/mL and 40 mg/mL are recommended; however, lower concentrations may be used if desired. Reconstitute vials with an appropriate IV diluent (see COMPATIBILITY AND STABILITY).

Vial Dosage Size	Amount of Diluent to be added
500 mg	4.8 mL
1 gm	9.6 mL

After reconstitution, each 1mL of solution contains approximately 100 mg equivalent of ceftriaxone. Withdraw entire contents and dilute to the desired concentration with the appropriate IV diluent.

STABILITY: This medicine should be used before the date shown after EXP on the pack.

STORAGE:

- Store at a temperature not exceeding 30°C.
- Protect from light.
- To be used within 6 hours after reconstitution at room temperature.
- Keep out of reach of children.

DOSAGE FORMS AND PACKS:

- Packs for I.M. injection containing: 1 vial with dry substance equivalent to 0.5 g or 1 g ceftriaxone, and 1 ampoule 2 ml or 4 ml of 1 % lidocaine solution.
- Packs for I.V. Injection: 1 vial with dry substance equivalent to 0.5 g or 1 g ceftriaxone, and 1 ampoule 5 ml or 2 ampoules 5 ml of sterile water for injections.

Keep medicaments out of reach of children.

Manufactured by

Medical Union Pharmaceuticals