FRONT

140.00 mm

210.00 mm

TXR Sterile Dry Powder for Injection

(Ceftriaxone Sodium)

ٹی ایکس آر سٹیرائل ڈرائی پاؤڈر فار انجیکشن

(سیفٹرائیگزون سوڈیم)

COMPOSITION:
TXR Injection 500mg IV
Each vial contains:
Ceftriaxone (as sodium) 500mg
(USP specifications)
TXR Injection 500mg IM
Each vial contains:
Ceftriaxone (as sodium) 500mg
(USP specifications)
TXR Injection 1g IV
Each vial contains:
Ceftriaxone (as sodium) 1g
(USP specifications)
TXR Injection 1g IM
Each vial contains:
Ceftriaxone (as sodium) 1g
(USP specifications)
TXR Injection 2g IV
Each vial contains:
Ceftriaxone (as sodium) 2g
(USP specifications)

DESCRIPTION:
TXR injection contains Ceftriaxone sodium which is a sterile, semisynthetic, broad-spectrum cephalosporin antibiotic for intravenous or intramuscular administration.

INDICATIONS:
TXR indicated in the following infections:
- **RESPIRATORY INFECTIONS**

including ear, nose and throat caused by Streptococcus pneumoniae, Staphylococcus aureus, Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella pneumoniae, Escherichia coli, Enterobacter aerogenes, Proteus mirabilis.
- **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, Pseudomonas aeruginosa, Serratia marcescens, Acinetobacter calcoaceticus, Bacteroides fragilis or 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 Neisseria gonorrhoeae. including both penicillinase- and non-penicillinase-producing strains, and pharyngeal gonorrhea caused by non-penicillinase-producing strains of Neisseria gonorrhoeae.
- **PELVIC INFLAMMATORY DISEASE**

caused by Neisseria gonorrhoeae. Ceftriaxone Like other cephalosporins, has no activity against Chlamydia trachomatis. Therefore, when cephalosporins are used in the treatment of patients with pelvic inflammatory disease and Chlamydia trachomatis is one of the suspected pathogens, appropriate anti-chlamydia! 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 meningitidis or Streptococcus pneumoniae. Ceftriaxone has also been used successfully in a limited number of cases of meningitis and shunt infection caused Staphylococcus epidem 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 1 gm dose of Ceftriaxone may reduce the incidence of postoperative infections in patients undergoing surgical procedures classified as contaminated or potentially contaminated (e.g.. vaginal or abdominal hysterectomy or cholecystectomy for chronic calculous 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).

MECHANISM OF ACTION
Ceftriaxone is a bactericidal agent that acts by inhibition of bacterial cell wall synthesis. Ceftriaxone has activity in the presence of some beta-lactamases, both penicillinases and cephalosporinases, of Gram-negative and Gram-positive bacteria.
Mechanism of Resistance
Resistance to Ceftriaxone is primarily through hydrolysis by beta-lactamase, alteration of penicillin-binding proteins (PBPs). and decreased permeability.

DOSAGE & ADMINISTRATION:
Ceftriaxone may be administered intravenously or intramuscularly.
General Instructions:
Do not use diluents containing calcium, such as Ringer's solution or Hartmann's solution; to reconstitute Ceftriaxone vials or to further dilute a reconstituted vial for I.V. administration because a precipitate can form. Precipitation of Ceftriaxone-calcium can also occur when Ceftriaxone mixed with calcium-containing solutions in the same I.V. administration line. Ceftriaxone must not be administered simultaneously usly with calcium-containing I.V. solutions, including continuous calcium-containing infusions such as parenteral nutrition via a Y-site. However, in patients other than neonates, Ceftriaxone and calcium-containing solutions may be administered sequentially of one another if the infusion lines are thoroughly flushed between infusions with a compatible fluid. There have been no reports of an interaction between Ceftriaxone and oral calcium- containing products or interaction between intramuscular Ceftriaxone and calcium-containing products (I.V. or oral).
Method of Administration
As a general rule, the solutions should be used immediately after preparation. Reconstituted solutions retain their physical and chemical stability for 6 hours at room temperature (or 24 hours in the refrigerator at 2-8°C) the solutions range in color from pale yellow to amber, depending on the concentration and length of storage. The coloration of the solutions is of no significance for the efficacy or tolerance of the drug.
Intramuscular Injection
For IM injection, Ceftriaxone 500mg is dissolved in 2ml and ceftriaxone 1g in 3.5ml of 1% lidocaine hydrochloride solution and injected within the body of a relativey large muscle. It is recommended that not more than 1g be injected at one site. The lidocaine hydrochloride solution should never beadministered intravenously.
Intravenous Injection
For IV injection, Ceftriaxone 500mg is dissolved in 5ml, Ceftriaxone 1g in 10ml and 2g in 20ml sterile water for injection. The intravenous administration should be given over 2-4 minutes.
Intravenous Infusion
The infusion should be given over at least 30 minutes. For IV infusion 2g Ceftriaxone is dissolved in 40ml of one of the following calcium-free infusion solutions, sodium chloride 0.9%, sodium chloride 0.45% + dextrose 2.5%, dextrose 5%, dextrose 10%, dextran 6% in dextrose 5%, hydroxyethyl starch 6-10%, water for injection. Ceftriaxone solutions should not be mixed withor piggy-backed into solutions containing other antimicrobial drugs or into diluent solutions other than those listed above, owing to possible incompatibility.
Dosage:
Ceftriaxone may be administered by deep intramuscular injection, slow intravenous injection, or as a slow intravenous infusion, after reconstitution of the solution according to the directions given below:
Dosage and mode of administration should be determined by the severity of the infection, susceptibility of the causative organism and the patient's condition. Under most circumstances a once-daily dose-or, in the specified indications, a singledose-will give satisfactory therapeutic results.
Standard dosage
Standard therapeutic dosage for adults and children (12 years and over) is 1g once daily. In severe cases or in infections caused by moderately sensitive organisms the dosagemay be raised to 4g, once daily.
Duration of therapy
The duration of therapy varies according to the course of disease. As with antibiotic therapy to general, administration of Ceftriaxone should be continued for a minimumof 48-72 hours after the patient has become afebrile or evidence of bacterial eradication has been obtained.
Combination therapy
In severe, life-threatening infections, the combination of Ceftriaxone sodium with aminoglycosides is indicated without awaiting the results of sensitivity tests. Because of physical incompatibility, the two drugs must be administered separately, not mixed in one syringe. Infections with Pseudomonas aeruginosa may require concomitant-treatment.

CONTRAINDICATIONS:
Hypersensitivity
It is contraindicated in patients with known hypersensitivity to Ceftriaxone, any of its excipients or to any other cephalosporin. Patients with previous hypersensitivity reactions to penicillin and other beta lactam antibacterial agents may be at greater risk of hypersensitivity to Ceftriaxone.

BACK

140.00 mm

210.00 mm

Neonates
Premature neonates: Ceftriaxone is contraindicated in premature neonates up to a postmenstrual age of 41 weeks (gestational age + chronological age).
Hyperbilirubinemic neonates: Hyperbilirubinemic neonates should not be treated with Ceftriaxone which can displace bilirubin from its binding to serum albumin, leading to a risk of bilirubin encephalopathy in these patients.
Lidocaine
Intravenous administration of Ceftriaxone solutions containing lidocaine is contraindicated. When lidocaine solution is used as a solvent with Ceftriaxone for intramuscular Injection, exclude all contraindications to lidocaine. Refer to the prescribing information of lidocaine.

WARNINGS:
Hypersensitivity Reactions
Before therapy with Ceftriaxone is instituted, careful inquiry should be made to determine whether the patient has had previous hypersensitivity reactions to cephalosporins, penicillins and other beta-lactam agents or other drugs. This product should be given cautiously to penicillin and other beta-lactam agent-sensitive patients. Antibacterial drugs 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. As with all beta-lactam antibacterial agents, serious and occasionally fatal hypersensitivity reactions (i.e., anaphylaxis) have been reported. In case of severe hypersensitivity reactions, treatment with Ceftriaxone must be discontinued immediately and adequate emergency measures must be initiated.
Interaction with Calcium-Containing Products
Do not use diluents containing calcium, such as Ringer's solution or Hartmann's solution, to reconstitute Ceftriaxone vials or to further dilute a reconstituted vial for IV administration because a precipitate can form.
Clostridium difficile-Associated Diarrhea
Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including Ceftriaxone, and may range in severity from mild diarrhea to fatal colitis.
Hemolytic Anemia
An Immune mediated hemolytic anemia has been observed in patients receiving cephalosporin class antibacterial including Ceftriaxone Severe cases of hemolytic anemia, including fatalities, have been reported during treatment in both adults and children.

PRECAUTIONS:
Development of Drug-resistant Bacteria
Prescribing Ceftriaxone in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the e patient and increases the risk of the development of drug-resistant bacteria. Prolonged use of Ceftriaxone may result in overgrowth of non-susceptible organisms. Careful observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken.
Patients with Renal or Hepatic Impairment
Ceftriaxone is excreted via both biliary and renal excretion. Therefore, patients with renal failure normally require no adjustment in dosage when usual doses of Ceftriaxone are administered.
Effect on Prothrombin Time
Monitor prothrombin time during Ceftriaxone treatment in patients with impaired vitamin K synthesis or low vitamin K stores (e.g., chronic hepatic disease and malnutrition).
Gallbladder Pseudolithiasis
Ceftriaxone-calcium precipitates in the gallbladder have been observed in patients receiving Ceftriaxone.
Urolithiasis and Post-Renal Acute Renal Failure
Ceftriaxone-calcium precipitates in the urinary tract have been observed in patients receiving Ceftriaxone and may be detected as sonographic abnormalities.
Pancreatitis
Cases of pancreatitis, possibly secondary to biliary obstruction, have been reported in patients treated with CEFTRIAXONE.

ADVERSE REACTIONS:
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 350 mg/mL and 5% (1/20) after IM administration of 250 mg/ml.
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS — injection site pain (0.6%) HYPERSENSITIVITY—rash (1.7%). Less frequently reported (1%) were pruritus, fever or chills.
INFECTIONS AND INFESTATIONS — genital fungal infection (0.1%).
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.
BLOOD AND LYMPHATIC DISORDERS — granulocytopenia (0.9%). coagulopathy (0.4%).
GASTROINTESTINAL — diarrhea/loose stools (2.7%). Less frequently reported (1%) were nausea or vomiting.
HEPATIC — elevations of aspartate aminotransferase (AST) (3.1%) or alanine aminotransferase (ALT) (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 — moniasis or vaginitis were reported occasionally (1%).
MISCELLANEOUS — diaphoresis and fushing were reported occasionally (1%).
INVESTIGATIONS — blood creatinine increased (0.6%).
Other rarely observed adverse reactions (0.1%) include abdominal pain, agranulocytosis, allergic pneumonitis, anaphylaxis, basophilla, billary thiasis, 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.

DRUG INTERACTIONS:
Ceftriaxone has an N-methylthiotriazine side-chain and may have the potential to increase the effects of anticoagulants and to cause a disulfiram-like reaction with alcohol. Unlike many cephalosporins, probenecid does not affect the renal excretion of ceftriaxone.

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

STORAGE & INSTRUCTIONS:
Store between 15-25°C.
Protect from heat, sunlight and moisture. Do not freeze.
Keep away from the reach of children.
To be sold on the prescription of a registered medical practitioner only.

HOW SUPPLIED:
TXR Injection 500mg IV
1vial + 5ml solvent [sterile water for injection]
25 vials
TXR Injection 500mg IM
1vial + 2ml solvent [1% lidocaine hydrochloride solution]
25 vials
TXR Injection 1g IV
1vial + 10ml solvent [sterile water for injection]
25 vials
TXR Injection 1g IM
1vial + 3.5ml solvent [1% lidocaine hydrochloride solution]
25 vials
TXR Injection 2g IV
1vial + 20ml solvent [sterile water for injection]
25 vials

خوراک وطریقہ استعمال:

ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات:

دوا کو ۱۵۔۲۵ ڈگری سینٹی گریڈ درجہ حرارت کے درمیان رکھیں۔
دھوپ، گرمی اور نمی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔
صرف رجسٹرڈ ڈاکٹر کے نسخہ کے مطابق فروخت کریں۔

Manufactured by:
PHARMASOL
PRIVATE LIMITED
Plot # 549,Sundar Industrial Estate,
Lahore, Pakistan.