Ceftro®
(Ceftriaxone)

Highnoon

COMPOSITION
Ceftro 250mg IM Injection: Each pack contains:
Vial: Ceftriaxone Sodium equivalent to Ceftriaxone 250mg
Ampoule: 1% Lignocaine HCl USP 2mL

Ceftro 250mg IV Injection: Each pack contains:
Vial: Ceftriaxone Sodium equivalent to Ceftriaxone 250mg
Ampoule: Sterile water for injection USP 5mL

Ceftro 500mg IM Injection: Each pack contains:
Vial: Ceftriaxone Sodium equivalent to Ceftriaxone 500mg
Ampoule: 1% Lignocaine HCl USP 2mL

Ceftro 500mg IV Injection: Each pack contains:
Vial: Ceftriaxone Sodium equivalent to Ceftriaxone 500mg
Ampoule: Sterile water for injection USP 5mL

Ceftro 1g IV injection: Each pack contains:
Vial: Ceftriaxone Sodium equivalent to Ceftriaxone 1g
Ampoule: Sterile water for injection USP 10mL

Ceftro 2g IV injection: Each pack contains:
Vial: Ceftriaxone Sodium equivalent to Ceftriaxone 2g
Ampoule: Sterile water for injection USP 20mL

DESCRIPTION
Ceftriaxone is a semi-synthetic, 3rd-generation cephalosporin antibiotic, with the high degree of stability to B-lactamases, broad-spectrum activity, and the effectiveness and convenience of long action.

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.

MICROBIOLOGY
Ceftriaxone binds to penicillin-binding proteins (PBP) located on walls of susceptible organisms and exerts strongly bactericidal action by inhibiting the synthesis of dipeptidoglycan, a substance necessary for bacterial cell wall strength and rigidity, thus killing the bacterium. Ceftriaxone is active against a wide variety of gram-positive and gram-negative bacteria and has potent activity against all the Enterobacteriaceae. Ceftriaxone is also active against some organisms resistant to first generation, second generation cephalosporins, currently available aminoglycoside and penicillins, e.g., Haemophilus influenzae, Neisseria meningitidis, Neisseria gonorrhoeae, Escherichia coli, Klebsiella pneumoniae, Serratia marcescens

Mechanism of Resistance
Resistance to ceftriaxone is primarily through hydrolysis by beta-lactamase, alteration of penicillin-binding proteins (PBPs), and decreased permeability.
Interaction with Other Antimicrobials: In an in vitro study, antagonistic effects have been observed with the combination of chloramphenicol and ceftriaxone.
Ceftriaxone has been shown to be active against most isolates of the following bacteria, both in vitro and in clinical infections as described:

- **Gram-negative bacteria**
  Acinetobacter calcoaceticus, Enterobacter aerogenes, Enterobacter cloacae, Escherichia coli, Haemophilus influenzae, Haemophilus parainfluenzae, Klebsiella oxytoca, Klebsiella pneumoniae, Moraxella catarrhalis, Morganella morganii, Neisseria gonorrhoeae, Neisseria meningitidis, Proteus mirabilis, Proteus vulgaris, Pseudomonas aeruginosa, Serratia marcescens.
- **Gram-positive bacteria**
  Staphylococcus aureus, Staphylococcus epidermidis, Streptococcus pneumoniae, Streptococcus pyogenes, Viridans group streptococci.
- **Anaerobic bacteria**
  Bacteroides fragilis, Clostridium species, Peptostreptococcus species.
  The following in vitro data are available, but their clinical significance is unknown. At least 90 percent of the following microorganisms exhibit an in vitro minimum inhibitory concentration (MIC) less than or
  equal to the susceptible breakpoint for ceftriaxone. However, the efficacy of ceftriaxone in treating clinical infections due to these microorganisms has not been established in adequate and well- controlled clinical trials.
- **Gram-negative bacteria**
  Citrobacter diversus, Citrobacter freundii, Providencia species (including Providencia rettgeri), Salmonella species (including Salmonella typhi), Shigella species.
- **Gram-positive bacteria**
  Streptococcus agalactiae
- **Anaerobic bacteria**
  Porphyromonas (Bacteroides) melaninogenicus, Prevotella (Bacteroides) bivius

Note: Methicillin-resistant Staphylococcus spp. and most strains of Enterococci (e.g. Streptococcus faecalis) are resistant to cephalosporins, including ceftriaxone. Many strains producing B-lactamase (e.g. Bacteriodes fragilis) are resistant to ceftriaxone. The susceptibility indicates that the antimicrobial is likely to inhibit growth of the pathogen if the antimicrobial compound reaches the concentration at the infection site necessary to inhibit growth of the pathogen. The resistant indicates that the antimicrobial is not likely to inhibit growth of the pathogen if the antimicrobial compound reaches the concentrations usually achievable at the infection site; other therapy should be selected.

PHARMACOKINETICS
Ceftriaxone has nonlinear dose-dependent pharmacokinetics because of its protein binding; about 85 to 95% is bound to plasma proteins depending on the concentration of Ceftriaxone. Mean peak plasma concentrations of about 40 and 80 micrograms/mL have been reported 2 hours alter intramuscular injection of 500 mg and 1g of Ceftriaxone respectively. The plasma half-life of Ceftriaxone is not dependent on the dose and varies between 6 and 9 hours; it may he prolonged in neonates. The half-life does not change appreciably in patients with moderate renal impairment, but it may he prolonged in severe impairment especially when there is also hepatic impairment. Ceftriaxone is widely distributed in body tissues and fluids. It crosses both inflamed and non-inflamed meninges, generally achieving therapeutic concentrations in the CSF. It crosses the placenta and low concentrations have been detected in breast milk. High concentrations occur in bile.
About 40 to 65% of a dose of Ceftriaxone is excreted unchanged in the urine, principally by glomerular filtration; the remainder is excreted in the bile anti is ultimately found in the faeces as unchanged drug and microbiologically inactive compounds.

INDICATIONS AND USAGE
Before instituting treatment with ceftriaxone, appropriate specimens should be obtained for isolation of the causative organism and for determination of its susceptibility to the drug. Therapy may be instituted prior to obtaining results of susceptibility testing. To reduce the development of drug-resistant bacteria and maintain the effectiveness of ceftriaxone for injection, USP and other antibacterial drugs, ceftriaxone for injection, USP should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy. Ceftriaxone for injection, USP is indicated for the treatment of the following infections when caused by susceptible organisms:

Lower Respiratory Tract Infections
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
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
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)
Urinary Tract Infections caused by Escherichia coli, Proteus mirabilis, Proteus vulgaris, Morganella morganii or Klebsiella pneumoniae.

Uncomplicated Gonorrhea (cervical/urethral and rectal)
Uncomplicated Gonorrhea caused by Neisseria gonorrhoeae, including both penicillinase- and nonpenicillinase-producing strains, and pharyngeal gonorrhea caused by nonpenicillinase-producing strains of Neisseria gonorrhoeae.

Pelvic Inflammatory Disease
Pelvic Inflammatory Disease caused by Neisseria gonorrhoeae. Ceftriaxone sodium, 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 antichlamydial coverage should be added.

Bacterial Septicemia
Bacterial Septicemia caused by Staphylococcus aureus, Streptococcus pneumoniae, Escherichia coli, Haemophilus influenzae or Klebsiella pneumoniae.

Bone and Joint Infections
Bone and Joint Infections caused by Staphylococcus aureus, Streptococcus pneumoniae, Escherichia coli, Proteus mirabilis, Klebsiella pneumoniae or Enterobacter species.

Intra-abdominal Infections
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
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 by Staphylococcus epidermidis and Escherichia coli.

Surgical Prophylaxis
The preoperative administration of a single 1g 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). When administered prior to surgical procedures for which it is indicated, a single 1g dose of ceftriaxone provides protection from most infections due to susceptible organisms throughout the course of the procedure.

DOSAGE AND ADMINISTRATION
Ceftriaxone may be administered intravenously or intramuscularly. Ceftriaxone for injection should be administered intravenously by infusion over a period of 30 minutes.
Adults:
The recommended adult dosages are outlined in below mentioned table. 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.

Recommended Dosing Schedule for Ceftriaxone for Injection

Site and type of infection	Dose	Frequency	Total daily dose
Usual adult dose	1g to 2g	once a day or in equally divided doses every 12 hours	should not exceed 4g*
Surgical prophylaxis	1g IV once	1/2 to 2 hours before surgery	
Skin and Skin Structure Infections	50 to 75mg per kg	once a day or in equally divided doses every 12 hours	should not exceed 2g
Meningitis	100mg per kg	once a day or in equally divided doses every 12 hours	should not exceed 4g*
Serious infections other than meningitis	50 to 75mg per kg	every 12 hours	should not exceed 2g

* Patients with hepatic impairment and significant renal impairment should not receive more than 2 grams per day of ceftriaxone.

Paediatric 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 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.
Neonates: Hyperbilirubinemic neonates, especially prematures, should not be treated with ceftriaxone for injection. 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.

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 administrated separately, not mixed in one syringe. Infections with Pseudomonas aeruginosa may require concomitant treatment

CONTRAINDICATIONS
- It is contraindicated in patients with known hypersensitivity to ceftriaxone or any other cephalosporin class of antibiotics. Patients with previous hypersensitivity reactions to penicillin and other beta lactam agents may be at greater risk of hypersensitivity to ceftriaxone.
- It is contraindicated in Neonates (≤28 days); Hyperbilirubinemic neonates, especially prematures, should not be treated with ceftriaxone for injection. It is shown that ceftriaxone can displace bilirubin from its binding to serum albumin, leading to a possible risk of bilirubin encephalopathy in these patients.
- It is contraindicated in neonates if they require (or are expected to require) treatment with calcium-containing I.V. solutions, including continuous calcium-containing infusions such as parenteral nutrition because of the risk of precipitation of ceftriaxone-calcium.

WARNINGS AND PRECAUTIONS
- Hypersensitivity: Before therapy with ceftriaxone is instituted, careful inquiry should be made to determine whether the patient has had previous hypersensitivity reactions to cephalosporins, penicillin's 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. As with other cephalosporins, 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 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 is mixed with calcium-containing solutions in the same I.V. administration line Ceftriaxone must not be administered simultaneously with calcium containing I.V. solutions, including continuous calcium containing infusions such as parenteral nutrition via a Y-site.
- Clostridium difficile associated diarrhoea (CDAD) has been reported with use of nearly all antibacterial agents, including ceftriaxone, and may range in severity from mild diarrhoea 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. CDAD must be considered in all patients who present with diarrhoea following antibiotic use. 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 ceftriaxone. 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.
- Superinfections with non-susceptible microorganism may occur as with other antibacterial agents.
- Prescribing ceftriaxone for injection 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 development of drug-resistant bacteria.
- 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. Dosage adjustments should 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 ceftriaxone dosage should not exceed 2g daily.
- Alterations in prothrombin times have occurred rarely in patients treated with ceftriaxone. Patients with impaired vitamin K synthesis orl low vitamin K stores (e.g., chronic hepatic disease and malnutrition) may require monitoring of prothrombin time during ceftriaxone treatment. Vitamin K administration (10 mg weekly) may be necessary
  if the prothrombin time is prolonged before or during therapy. 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.
- Ceftriaxone for injection 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; some of these patients also had symptoms of gallbladder disease. The condition appears to be transient and reversible upon discontinuation of ceftriaxone for injection and institution of conservative management. Therefore, ceftriaxone should be discontinued in patients who develop signs and symptoms suggestive of gallbladder disease.
- Cases of pancreatitis, possibly secondary to biliary obstruction, have been reported rarely in patients treated with ceftriaxone. Most patients presented with risk factors for biliary stasis and biliary sludge (preceding major therapy, severe illness, total parenteral nutrition).
- Patients should be counselled that antibacterial drugs including ceftriaxone for injection should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When ceftriaxone for injection 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.
- Diarrhoea 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. During prolonged treatment, complete blood count should be monitored at regular interval.
- Patients with overt or known subclinical diabetes mellitus or carbohydrate intolerance; As with other dextrose-containing solutions, Ceftriaxone for injection and dextrose injection should be prescribed with caution in patients with overt or known subclinical diabetes mellitus or carbohydrate intolerance for any reason.
- 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. The probability of such precipitates appears to be greatest in pediatric patients. Patients may be asymptomatic or may develop symptoms of urolithiasis, and ureteral obstruction and post-renal acute renal failure. The condition appears to be reversible upon discontinuation of ceftriaxone and institution of appropriate management. Ensure adequate hydration in patients receiving ceftriaxone. Discontinue ceftriaxone in patients who develop signs and symptoms suggestive of urolithiasis, oliguria or renal failure and/or the sonographic findings described above.
- Hypersensitivity to dextrose products; Hypersensitivity reactions, including anaphylaxis, have been reported with administration of dextrose products. These reactions have been reported in patients receiving high concentrations of dextrose (i.e. 50% dextrose)1. The reactions have also been reported when corn-derived dextrose solutions were administered to patients with or without a history of hypersensitivity to corn products.
- Neurological adverse reactions: Serious neurological adverse reactions have been reported during with ceftriaxone use. These reactions include encephalopathy (disturbance of consciousness including somnolence, lethargy, and confusion), seizures, myoclonus, and non-convulsive status epilepticus. Some cases occurred in patients with severe renal impairment who did not receive appropriate dosage adjustment. If neurological adverse reactions associated with ceftriaxone for injection and dextrose injection therapy occur, discontinue ceftriaxone for injection and dextrose injection and institute appropriate supportive measures. Make appropriate dosage adjustments.

Pregnancy
There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproductive studies are not always predictive of human response, 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 ceftriaxone is administered to a nursing woman.

Paediatric Use
Safety and effectiveness of ceftriaxone in neonates, infants and paediatric patients have been established for the dosages described. It has shown that ceftriaxone, like some other cephalosporins, can displace bilirubin from serum albumin. Ceftriaxone should not be administered to hyperbilirubinemic neonates, especially prematures.

Geriatric Use
The dosage adjustments are not necessary for geriatric patients with ceftriaxone dosages up to 2 grams per day.

ADVERSE REACTIONS
The reported adverse events are; pain at site of injection, induration and tenderness, phlebitis, warmth, tightness or induration at site of injection, rash, pruritus, fever or chills, eosinophilia, thrombocytosis, leukopenia, anaemia, hemolytic anaemia, neutropenia, lymphopenia, thrombocytopenia and prolongation of the prothrombin time, diarrhoea, nausea, vomiting, dysgeusia, pseudomembranous colitis, elevations of SGOT or SGPT, elevations of alkaline phosphatase and bilirubin, elevations of the BUN, creatinine and the presence of casts in the urine, headache, dizziness, moniliasis or vaginitis, diaphoresis and flushing, 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, hypersensitivity reactions, ceftriaxone calcium precipitates neurological effects, encephalopathy, myoclonus, and nonconvulsive status epilepticus.
The additional reported adverse events are stomatitis, glossitis, oliguria, exanthema, allergic dermatitis, urticaria, edema, isolated cases of severe cutaneous adverse reactions (erythema multiforme, Stevens-Johnson syndrome or Lyell's syndrome/toxic epidermal necrolysis), allergic reactions, drug fever, serum sickness-like reaction, renal dysfunction, toxic nephropathy, reversible hyperactivity, hypertonia, hepatic dysfunction including cholestasis, aplastic anaemia, haemorrhage, super infection, 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. If seizures associated with drug therapy occur, the drug should be discontinued. Anticonvulsant therapy can be given if clinically indicated.

DRUG INTERACTION
- Vancomycin, amsacrine, aminoglycosides, and fluconazole are physically incompatible with ceftriaxone in admixtures.
- Precipitation of ceftriaxone-calcium can occur when Ceftriaxone for injection and dextrose injection is mixed with calcium-containing solutions in the same IV administration line.
- Ceftriaxone for injection and dextrose injection must not be administered simultaneously with calcium-containing IV solutions. Ceftriaxone for injection and dextrose injection and calcium-containing solutions may be administered sequentially.

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

METHOD FOR PREPARATION
As a general rule, the solution 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 2-8OC). The solutions range in color from pale yellow to amber, depending on the concentration and length of storage. The coloration of the solution is of no significance for the efficacy or tolerance of the drug.
Intramuscular injection (for I.M. injection), Ceftro 250mg or 500mg is dissolved in 2mL of lignocaine (lidocaine) hydrochloride 1% solution and injected well within the body of relatively large muscle. It is recommended that not more than 1gm be injected at one site.
The lignocaine (lidocaine) hydrochloride solution should not be administered intravenously.
Intravenous Injection (for I.V. injection),Ceftro 250mg and 500mg is dissolved in 5mL and Ceftro 1gm in 10mL 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 I.V. infusion 2gm Ceftro 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%, hydroxy ethyle starch 6-10%, water for injection.
Ceftriaxone solution should not be mixed with piggybacked into solutions containing other antimicrobial drugs or into diluent solutions other than those listed above, owing to possible incompatibility.

Compatibility and Stability
Ceftriaxone has been shown to be compatible with (metronidazole hydrochloride). The concentration should not exceed 5 to 7.5 mg/mL metronidazole hydrochloride with ceftriaxone 10 mg/mL as an admixture. The admixture is stable for 24 hours at room temperature only in 0.9% sodium chloride injection or 5% dextrose in water. Metronidazole at concentrations greater than 8 mg/mL will precipitate. Do not refrigerate the admixture as precipitation will occur. Vancomycin, amsacrine, aminoglycosides, and fluconazole are physically incompatible with ceftriaxone in admixtures. When any of these drugs are to be administered concomitantly with ceftriaxone by intermittent intravenous infusion, it is recommended that they be given sequentially, with thorough flushing of the intravenous lines (with one of the compatible fluids) between the administrations.

Do not use diluents containing calcium, such as Ringer's solution or Hartmann's solution, to reconstitute ceftriaxone for injection or to further dilute a reconstituted vial for I.V. administration. Particulate formation can result.

DOSAGE AND INSTRUCTIONS
To be sold and used on the prescription of a registered medical practitioner only. Keep out of reach of children. Do not store above 30°C. Keep in a dry place. Protect from light.

PRESENTATION
Ceftro 250mg IM Injection
1 vial of 250mg ceftriaxone and 1 ampoule of 2mL lignocaine hydrochloride 1%.

Ceftro 500mg IM Injection
1 vial of 500mg ceftriaxone and 1 ampoule of 2mL lignocaine hydrochloride 1%.

Ceftro 250mg IV Injection
1 vial of 250mg ceftriaxone and 1 ampoule of 5mL Sterile water for injection.

Ceftro 500mg IV Injection
1 vial of 500mg ceftriaxone and 1 ampoule of 5mL Sterile water for injection.

Ceftro 1g IV Injection
1 vial of 1g ceftriaxone and 1 ampoule of 10mL Sterile water for injection.

Ceftro 2g IV Injection
1 vial of 2g ceftriaxone and 1 ampoule of 20mL Sterile water for injection.

سیفٹرو®
(سیفٹرائی ایگزون)

خوراک و ہدایات:
صرف مستند ڈاکٹر کے نسخہ کے مطابق ہی دوا فروخت اور استعمال کی جائے۔
بچوں کی پہنچ سے دور رکھیں۔ 30°C سے زیادہ درجہ حرارت پر نہ رکھیں۔
خشک جگہ پر رکھیں۔ روشنی سے بچائیں۔

Manufactured by
CUREXA HEALTH (PVT) LTD
Plot No. 517, Sundar Industrial Estate,
Lahore, Pakistan.

Marketed by
HIGHNOON LABORATORIES LTD
17.5 KM, Multan Road, Lahore, Pakistan.
www.highnoon-labs.com

Item Code No. 5130001C