TRIAX

COMPOSITION:

Triax 250mg: Each vial contains Ceftriaxone Sodium U.S.P equivalent to 250mg sterile Ceftriaxone.
Triax 500mg: Each vial contains Ceftriaxone Sodium U.S.P equivalent to 500mg sterile Ceftriaxone.
Triax 1gm: Each vial contains Ceftriaxone Sodium U.S.P equivalent to 1gm sterile Ceftriaxone.
Triax 2gm: Each vial contains Ceftriaxone Sodium U.S.P equivalent to 2gm sterile Ceftriaxone
Product conforms to the USP Specifications.

DESCRIPTION:

Ceftriaxone (Triax) is a sterile, semisynthetic, broad-spectrum Cephalosporin antibiotic for intravenous or intramuscular administration.

MICROBIOLOGY:

The bactericidal activity 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 beta-lactamases, both Penicillinases and Cephalosporinases, of Gram-positive and Gram-negative bacteria.

INDICATIONS:

Ceftriaxone (Triax) is indicated for the treatment of the following infections: Lower respiratory tract infections, Acute bacterial otitis media, Skin and skin structure infections, Urinary tract infections, Uncomplicated gonorrhea, Pelvic inflammatory disease, Bacterial septicemia, Bone and joint infections, Intra-abdominal infections, Meningitis and Surgical prophylaxis.

DOSAGE & ADMINISTRATION:

Adults and children over twelve years: The usual dosage is 1-2gm of Ceftriaxone (Triax) administered once daily (every 24 hours). In severe cases or in infections caused by moderately sensitive organisms, the dosage may be raised to 4gm, administered once daily. Neonates, infants and children up to twelve years: Neonates (up to two weeks) a daily dose of 20-50 mg/kg body weight once daily, not to exceed 50 mg/kg.Infants and children (three weeks to twelve years) a daily dose of 20-80 mg/kg. For children with body weight of 50 kg or more, the usual adult dosage should be used. Intravenous doses of 50mg or more per kg should be given by infusion over at least 30 minutes. Elderly patients: The dosage recommended for adults require no modification in the case of geriatric patients.
Duration of therapy: The duration of therapy varies according to the course of the disease. As with antibiotic therapy in general, administration of Ceftriaxone (Triax) should be continued for a minimum of 48-72 hours after the patient has become afebrile or evidence of bacterial eradication has been obtained.
Combination therapy: Synergy between Ceftriaxone (Triax) and Aminoglycosides has been demonstrated with many Gram-negative bacilli under experimental conditions. It should be considered in severe, life-threatening infections due to microorganisms such as Pseudomonas aeruginosa. Because of physical incompatibility the two drugs must be administered separately at the recommended dosages.

Wilshire
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CONTINUE

TRIAX

DIRECTIONS FOR USE:

Reconstituted solutions retain their physical and chemical stability for six hours at room temperature (or 24 hours at 5OC. They range in colour from pale yellow to amber, depending on the concentration and the length of storage.
Intramuscular injections: For I.M. injections, Ceftriaxone (Triax) 250mg or 500mg is dissolved in 2ml and Ceftriaxone (Triax) 1gm in 3.5ml of 1% lignocaine HCl injection and administered by deep intragluteal injection. It is recommended that not more than 1gm be injected on either side. The lignocaine HCl injection must never be administered intravenously.
Intravenous injections: For I.V. injection, Ceftriaxone (Triax) 250mg and 500mg is dissolved in 5ml and Ceftriaxone (Triax) 1gm into 10ml of sterile water for injection and then administered by I.V. injection lasting two to four minutes.
Intravenous infusion: The infusion should last at least 30 minutes. For I.V. infusion, 2g Ceftriaxone (Triax) 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%, levulose 5%, dextran 6% in dextrose, sterile water for injections. Ceftriaxone (Triax) solutions should not be mixed with or piggybacked into solutions containing other antimicrobial drugs or into diluent solutions other than those listed above, owing to possible incompatibility.

CONTRAINDICATIONS:

Ceftriaxone (Triax) is contraindicated in patients with known hypersensitivity to Ceftriaxone, any of its excipients or to any other Cephalosporin.
Premature Neonates: Ceftriaxone (Triax) 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 (Triax). Ceftriaxone can displace bilirubin from its binding to serum albumin, leading to a risk of bilirubin encephalopathy in these patients.
Neonates requiring Calcium containing I.V. Solutions: Ceftriaxone (Triax) is contraindicated in neonates (≤ 28 days) if they require (or are expected to require) treatment with Calcium containing I.V. solutions.

WARNINGS:

Do not use diluents containing Calcium, such as Ringer's solution or Hartmann's solution, to reconstitute Ceftriaxone (Triax) 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 (Triax) is mixed with Calcium containing solutions in the same I.V. administration line. Ceftriaxone (Triax) must not be administered simultaneously with Calcium containing I.V. solutions.

PREGNANCY AND LACTATION:

Pregnancy: Pregnancy Category B. There are no adequate and well-controlled studies in pregnant women. 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 (Triax) is administered to a nursing woman.

TRIAX

ADVERSE DRUG REACTIONS:

LOCAL REACTIONS: Phlebitis, Injection site pain, Induration and Tenderness.
HYPERSENSITIVITY: Rash, Pruritus, Fever or Chills.
INFECTIONS AND INFESTATIONS: Genital fungal infection.
HEMATOLOGIC: Eosinophilia, Thrombocytosis and Leukopenia, Anemia, Hemolytic anemia, Neutropenia, Lymphopenia, Thrombocytopenia and Prolongation of the Prothrombin time.
BLOOD AND LYMPHATIC DISORDERS: Granulocytopenia and Coagulopathy.
GASTROINTESTINAL: Diarrhea/loose stools, Nausea or vomiting and Dysgeusia. The onset of pseudomembranous colitis symptoms may occur during or after antibacterial treatment.
CENTRAL NERVOUS SYSTEM: Headache or Dizziness.
GENITOURINARY: Moniliasis or Vaginitis.
MISCELLANEOUS: Diaphoresis and Flushing.
INVESTIGATIONS: Blood Creatinine increased

INSTRUCTIONS:

Store in a cool & dry place below 25 °C.
Protect from light, heat and moisture.
Keep out of reach of children.

PRESENTATION:

Triax 250mg (I.V.): Pack of injection containing 1 vial of dry substance equivalent to 250mg sterile Ceftriaxone along with 5ml WFI ampoule.
Triax 250mg (I.M.): Pack of injection containing 1 vial of dry substance equivalent to 250mg sterile Ceftriaxone along with ampoule of 2ml 1% lignocaine HCl injection.
Triax 500mg (I.V.): Pack of injection containing 1 vial of dry substance equivalent to 500mg sterile Ceftriaxone along with 5ml WFI ampoule.
Triax 500mg (I.M.): Pack of injection containing 1 vial of dry substance equivalent to 500mg sterile Ceftriaxone along with ampoule of 2ml 1% lignocaine HCl injection.
Triax 1gm (I.V.): Pack of injection containing 1 vial of dry substance equivalent to 1gm sterile Ceftriaxone along with 10ml WFI ampoule.
Triax 2gm (I.V.): Pack of injection containing 1 vial of dry substance equivalent to 2gm sterile Ceftriaxone along with WFI ampoule.