PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER
(TRIXON) CEFTRIAXONE FOR INJECTION USP 500/1000/2000 MG

(Ceftriaxone Sodium USP**)**

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, health care provider or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist.

In this leaflet:

1. **What Trixon Injections is and what it is used for**
2. **Before you use Trixon Injections.**
3. **How to use Trixon Injections.**
4. **Possible side effects.**
5. **How to store Trixon Injections.**
6. **Further information.**

1. WHAT TRIXON INJECTIONS IS AND WHAT IT IS USED FOR

Trixon Injections contain active ingredient Ceftriaxone, which is an third-generation cephalosporins antibiotic given to adults and children (including newborn babies). It works by killing bacteria that cause infections. It belongs to a group of medicines called cephalosporins. It is indicated for the treatment of the following infections: in adults and children including term neonates (from birth): Bacterial Meningitis, Community acquired pneumonia hospital acquired pneumonia , acute otitis media, intra-abdominal infections, complicated urinary tract infections (including pyelonephritis), infections of bones and joints, complicated skin and soft tissue infections, gonorrhea, syphilis, bacterial endocarditis. It may be used: For treatment of acute exacerbations of chronic obstructive pulmonary disease in adults. For treatment of disseminated Lyme borreliosis (early (stage II) and late (stage III)) in adults and children including neonates from 15 days of age. For pre-operative prophylaxis of surgical site infections. In the management of neutropenic patients with fever that is suspected to be due to a bacterial infection. In the treatment of patients with bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above. It should be co-administered with other antibacterial agents whenever the possible range of causative bacteria would not fall within its spectrum. Consideration should be given to official guidelines on the appropriate use of antibacterial agents.

2. BEFORE YOU USE TRIXON INJECTIONS

Do not use Trixon Injections: Hypersensitivity to ceftriaxone, or to any other cephalosporin. History of severe hypersensitivity to any other type of beta-lactam antibacterial agent (penicillins, monobactams and carbapenems). Ceftriaxone is contraindicated in: Premature neonates up to a postmenstrual age of 41 weeks (gestational age + chronological age). **Full-term neonates (up to 28 days of age):** with hyperbilirubinaemia, jaundice, or who are hypoalbuminaemic or acidotic because these are conditions in which bilirubin binding is likely to be impaired if they require (or are expected to require) intravenous calcium treatment, or calcium-containing infusions due to the risk of precipitation of a ceftriaxone-

calcium salt. In vitro studies have shown that ceftriaxone can displace bilirubin from its serum albumin binding sites leading to a possible risk of bilirubin encephalopathy in these patients. Contraindications to lidocaine must be excluded before intramuscular injection of ceftriaxone when lidocaine solution is used as a solvent. Ceftriaxone solutions containing lidocaine should never be administered intravenously.

Take special care with Trixon Injections: Warnings and Precautions: Talk to your doctor or pharmacist or nurse before you are given Ceftriaxone for injection in case of the following: Do not exceed the prescribed dose. Your doctor may also have to monitor your treatment more closely, alter your dose or give you another medicine. You have recently received or are about to receive products that contain calcium. You have recently had diarrhoea after having an antibiotic medicine. You have ever had problems with your gut, in particular colitis (inflammation of the bowel). You have liver or kidney problems. You have gallstones or kidney stones. You have other illnesses, such as haemolytic anaemia (a reduction in your red blood cells that may make your skin pale yellow and cause weakness or breathlessness). You are on a low-sodium diet. You experience or have previously experienced a combination of any of the following symptoms: rash, red skin, blistering of the lips, eyes and mouth, skin peeling, high fever, flu-like symptoms, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes. If you need a blood or urine test: If you are given Ceftriaxone for injection for a long time, you may need to have regular blood tests. Ceftriaxone for injection can affect the results of urine tests for sugar and a blood test known as the Coombs' test. If you are having tests, tell the person taking the sample that you have been given Ceftriaxone for injection. If you are diabetic or need to have your blood glucose level monitored, you should not use certain blood glucose monitoring systems that may estimate blood glucose incorrectly while you are receiving Ceftriaxone. If you use such systems, check the instructions for use and tell your doctor, pharmacist or nurse. Alternative testing methods should be used if necessary. **Using other medicines:** Please tell your doctor, pharmacist or nurse if you are using, have recently used or might use any other medicines. Ceftriaxone Antibiotics may diminish the therapeutic effect of BCG Typhoid Vaccine. Calcium Salts (Intravenous) may enhance the adverse/toxic effect of Ceftriaxone. Ceftriaxone binds to calcium forming an insoluble precipitate. Probenecid may increase the serum concentration of Ceftriaxone. Ceftriaxone may enhance the anticoagulant effect of Vitamin K. **Pregnancy and breast-feeding: Pregnancy:** It crosses the placental barrier. There are limited amounts of data from the use of ceftriaxone in pregnant women. It should only be administered during pregnancy and in particular in the first trimester of pregnancy if the benefit outweighs the risk. **Lactation:** It is excreted into human milk in low concentrations but at therapeutic doses of ceftriaxone no effects on the breastfed infants are anticipated. It should only be given during lactation women if the benefit outweighs the risk. **Driving and using machines: During treatment with ceftriaxone, undesirable effects may occur (e.g. dizziness), which may influence the ability to drive and use machines. Patients should be cautious when driving or operating machinery.** It contain powder for solution for injection 69.5 mg sodium i.e. is essentially "sodium free".

HOW TO USE TRIXON INJECTIONS

In all cases, strictly follow the physician's prescription. Ceftriaxone for injection is usually prepared & given by physician or pharmacist or nurse. It can be given as. A drip IV infusion, or as an injection directly into a vein Intravenous (IV), or into a muscle Intramuscular (IM). **Route of administration:** Ceftriaxone for injection is usually prepared & given by physician or pharmacist or nurse. It can be given as. A drip IV infusion, or as an injection directly into a vein

Intravenous (IV), or into a muscle Intramuscular (IM). It will not be mixed with or given to you at the same time as calcium-containing injections. Intravenous (IV): It can be administered by intravenous infusion over at least 30 minutes (preferred route) or by slow intravenous injection over 5 minutes. It should be given over 5 minutes preferably in larger veins. Intravenous doses of 50 mg/kg or more in infants and children up to 12 years of age should be given by infusion. In neonates, intravenous doses should be given over 60 minutes to reduce the potential risk of bilirubin encephalopathy. Intramuscular (IM): It can be administered by deep intramuscular injection. Intramuscular injections should be injected well within the bulk of a relatively large muscle and not more than 1 g should be injected at one site. Ceftriaxone is contraindicated in neonates (≤28 days of age), including continuous calcium-containing infusions such as parenteral nutrition, because of the risk of precipitation of Ceftriaxone-calcium. Diluents containing calcium (e.g. Ringer' solution or Hartmann&#39 solution), should not be used to reconstitute. Ceftriaxone and calcium-containing solutions must not be mixed or administered simultaneously. For pre-operative prophylaxis of surgical-site infections, Ceftriaxone should be administered 30–90 minutes prior to surgery. The dose depends on the severity, susceptibility, site and type of infection and on the age and hepatic-renal function of the patient. The doses recommended in the below are the generally recommended doses in these indications. In particularly severe cases, doses at the higher end of the recommended range should be considered.

Dosage information: Adults and children over 12 years of age (≥ 50 kg): Ceftriaxone Dosage: 1-2 g or 2 g, treatment frequency: Once daily, as per dignosed indications: Acute otitis media: A single intramuscular dose of 1-2 g can be given. Pre-operative prophylaxis of surgical site infections 2 g as a single pre-operative dose. Gonorrhoea: 500 mg as a single intramuscular dose. Syphilis: 500 mg-1 g once daily increased to 2 g once daily for neurosyphilis for 10-14 days. The dose recommendations in syphilis, including neurosyphilis, are based on limited data. National or local guidance should be taken into consideration. **Paediatric Patients: Neonates, Infants and Children 15 Days to 12 Years of Age (<50 kg).** For children with bodyweight of ≥50 kg, the usual adult dosage should be given: 50–80 mg/kg once daily or 80–100 mg/kg (max 4 g) once daily. Neonates 0–14 Days of Age: Ceftriaxone is contraindicated in premature neonates up to a postmenstrual age of 41 weeks (gestational age + chronological age): 20–50 mg/kg once daily or 50 mg/kg once daily. A maximum daily dose of 50 mg/kg should not be exceeded. In documented bacteraemia, the higher end of the recommended dose range should be considered. Twice daily (12 hourly) administration may be considered where doses greater than 2 g daily are administered. **Acute otitis media:** A single intramuscular dose of 50 mg/kg can be given.Pre-operative prophylaxis of surgical site infections 20-50 mg/kg as a single pre-operative dose. Gonorrhoea: 500 mg as a single intramuscular dose. Syphilis: 50 mg/kg once daily for 10-14 days.. The dose recommendations in syphilis, including neurosyphilis, are based on limited data. National or local guidance should be taken into consideration. **Duration of Therapy:** It varies according to the course of the disease. As with antibiotic therapy in general, administration of Ceftriaxone should be continued for 48–72 hours after the patient has become afebrile or evidence of bacterial eradication has been achieved. **Older people:** The dosages recommended for adults require no modification in older people provided that renal and hepatic function is satisfactory. Patients with renal impairment: In patients with impaired renal function, there is no need to reduce the dosage of ceftriaxone provided hepatic function is not impaired. Only in cases of preterminal renal failure (creatinine clearance < 10 ml/min) should the ceftriaxone dosage not exceed 2 g daily. In patients undergoing dialysis no additional supplementary dosing is required following the dialysis. Ceftriaxone is not removed by peritoneal or haemodialysis. Close clinical monitoring for safety

and efficacy is advised. Patients with severe hepatic and renal impairment: In patients with both severe renal and hepatic dysfunction, close clinical monitoring for safety and efficacy is advised. **How Trixon Injections will be given to you:** Ceftriaxone for injection is usually prepared & given by physician or pharmacist or nurse. It can be given as. A drip IV infusion, or as an injection directly into a vein Intravenous (IV), or into a muscle Intramuscular (IM). **If you more Trixon Injections than you should:** In overdose, the symptoms of nausea, vomiting and diarrhoea can occur. It concentrations cannot be reduced by haemodialysis or peritoneal dialysis. There is no specific antidote. Treatment of overdose should be symptomatic. Supportive care is advised. **If you forget to Trixon Injections:** If you miss an injection, you should have it as soon as possible. However, if it is almost time for your next injection, skip the missed injection. Do not take a double dose (two injections at the same time) to make up for a missed dose. If you stop taking Ceftriaxone for injection: Do not stop taking Ceftriaxone for injection unless your doctor tells you to. If you have any further questions on the use of this medicine, ask your doctor or nurse.

3.POSSIBLE SIDE EFFECTS

Like any active substance, this medicine may induce, in some patient's undesirable effects to a greater or lesser degree. Infections and infestations: Uncommon: Genital fungal infection. Rare: Pseudomembranous colitis. Not Known: Superinfection. Blood and lymphatic system disorders: Common: Eosinophilia Leucopenia Thrombocytopenia. Uncommon: Granulocytopenia Anaemia Coagulopathy. Not Known: Haemolytic anaemia Agranulocytosis. Immune system disorders: Not Known: Anaphylactic shock, anaphylactic reaction, anaphylactic reaction, Hypersensitivityb, Jarisch-Herxheimer reaction. Nervous system disorders: Uncommon: Headache Dizziness. Rare: Encephalopathy. Not Known: Convulsion. Ear and labyrinth disorders: Not Known: Vertigo. Respiratory, thoracic and mediastinal disorders: Rare: Bronchospasm. Gastrointestinal disorders: Common: Diarrhoeab, Loose stools. Uncommon: Nausea, Vomiting. Not Known: Pancreatitisb, Stomatitis, Glossitis. Hepatobiliary disorders: Common: Hepatic enzyme increased. Not Known: Gall bladder precipitation, Kernicterus Hepatitisc, Hepatitis cholestatic. Skin and subcutaneous tissue disorders: Common: Rash. Uncommon: Pruritus. Rare: Urticaria. Not Known: Stevens Johnson Syndrome, Toxic epidermal necrolysisb Erythema Multiforme, Acute generalised exanthematous pustulosis, Drug reaction with eosinophilia and systemic symptoms (DRESS). Renal and urinary disorders: Rare: Haematuria, Glycosuria. Not Known: Oliguria, Renal precipitation. General disorders and administration site conditions. Uncommon: Phlebitis, Injection site pain, Pyrexia. Rare: Oedema, Chills. Investigations: Uncommon: Blood creatinine increased. Not Known: Coombs test false positive, Galactosaemia test false positive, Non enzymatic methods for glucose determination false positive. Do not hesitate to ask your physician or pharmacist for advice and to report any undesirable effect not mentioned in this leaflet.

4.HOW TO STORE TRIXON INJECTIONS

Keep this medicine out of the sight and reach of children. Store below 30°C. Protect from light. Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month. Once the medicine has been mixed with sterile water for injections the solution should be used straight away. Any unused liquid should be disposed of safely. Your doctor will check that the solution contains no particles and is not discoloured before using it.

5.FURTHER INFORMATION

What Trixon Injections contains: The active substances is Ceftriaxone Sodium USP (sterile lyophilized) equivalent to anhydrous Ceftriaxone 500 mg/1000 mg/2000 mg. A Dry Powder: White, almost white or tan to brown free flowing powder odourless and having a bitter taste filled in 10 ml Clear Glass Vial USP Type - III Having 20 mm Grey Bromobutyl RFU Sterile Rubber Stopper & 20mm Blue Flip Off Seal, with One Ampoule of 10 ml Sterilized Water for Injections BP in printed carton along with package insert. After Reconstitution: Produces a light yellow to light brown transparent solution when reconstituted in water for injection.

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