

Composition

Maxzon 250 mg IM injection: Each vial contains sterile Ceftriaxone Sodium USP equivalent to Ceftriaxone 250 mg and each ampoule contains 2 ml Lidocaine Hydrochloride USP 1% solution.

Maxzon 500 mg IM injection: Each vial contains sterile Ceftriaxone Sodium USP equivalent to Ceftriaxone 500 mg and each ampoule contains 2 ml Lidocaine Hydrochloride USP 1% solution.

Maxzon 1 gm IV injection: Each vial contains sterile Ceftriaxone Sodium USP equivalent to Ceftriaxone 1 gm and each ampoule contains 10 ml water for Injection USP.

Maxzon 2 gm IV injection: Each vial contains sterile Ceftriaxone Sodium USP equivalent to Ceftriaxone 2 gm and also contains 2 ampoules of 10 ml water for Injection USP.

Pharmacology

Ceftriaxone is a third generation broad spectrum parenteral cephalosporin antibiotic. Ceftriaxone interferes with the synthesis of bacterial cell wall by inhibiting transpeptidase enzyme. As a result the bacterial cell wall is weakened, the cell swells and then ruptures.

Indication

Ceftriaxone is indicated for the treatment of the following major infections when caused by susceptible organisms: Renal and urinary tract infections, Lower respiratory tract infections, particularly Pneumonia, Gonococcal infections, Skin and soft tissue, Bone and joint infections, Bacterial meningitis, Serious bacterial infections e.g. Septicemia, ENT infections, Infections in cancer patients, Prevention of postoperative infection, Preoperative prophylaxis of infections associated with surgery & Typhoid fever.

Dose & Administration

a) *Route of administration: IV/IM*

● **Adults:** The usual adult daily dose is 1-2 gm once daily, (or twice daily in equally divided doses) depending on the type and severity of infection. The daily dose may be increased, but should not exceed 4 gm. In elderly patients, the dosages do not require modification provided that renal and hepatic functions are satisfactory.

● **Children under 12 years:** The recommended total daily dose is 50 to 75 mg/kg once daily (or twice daily in equally divided doses). In severe infections, up to 80 mg/kg body weight daily may be given. The total daily dose should not exceed 2 gm. In the treatment of meningitis, the initial dose of 100 mg/kg body weight (not to exceed 4 gm daily) once daily (or twice daily in equally divided doses), is recommended. As soon as the causative organism has been identified and its sensitivity, the doses can be reduced accordingly. The usual duration of therapy in meningitis is 7 to 14 days.

Preparation of Solutions for Intravenous/Intramuscular Injections

For Intravenous Injection: 1 gm Maxzon dry powder should be dissolved in 10 ml of water for injection USP with vigorous shaking or 2 gm Maxzon dry powder should be dissolved in 20 ml of water for injection USP with vigorous shaking. The injection should be administered over 2-4 minutes, directly into the vein or via the tubing of an intravenous infusion.

For Intramuscular Injection: 250 & 500 mg Maxzon dry powder should be dissolved in 2 ml of Lidocaine HCL BP 1% solution with vigorous shaking. It should be injected well within the body of a relatively large muscle. It is recommended that not more than 1g be injected at one site. The lidocaine solution should never be administered intravenously.

Contra-indication

Ceftriaxone should not be given to patients with a history of hypersensitivity to cephalosporin antibiotics or any other components of this product. It is contraindicated in premature infants during the rest 6 weeks of life. Its safety in human pregnancy has not been established. 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.

Warning & Precaution

Ceftriaxone must not be administered simultaneously with calcium containing products. It must be prescribed with caution in individuals with a history of gastrointestinal disease, especially colitis.

Side effects

Ceftriaxone is generally well tolerated. A few side effects such as:

a) **Common:** Gastrointestinal effects include diarrhea, nausea and vomiting, stomatitis and glossitis. Cutaneous reactions include rash, pruritus, urticaria, edema & erythema multiforme.

b) **Rare:** Hematological reactions include eosinophilia, thrombocytosis, leukopenia, and neutropenia. Hepatic reactions include elevations of SGOT or SGPT, bilirubinemia. CNS reactions include headache, hyperactivity, nervousness, sleep disturbances, confusion, hypertonia, and dizziness were reported. Local phlebitis occurs rarely following intravenous administration but can be minimized by slow injections over 2-4 minutes.

Use in Pregnancy & Lactation

Ceftriaxone has not been associated with adverse effects on fetal development in laboratory animals, but its safety in human pregnancy has not been established. Therefore, it should not be used in pregnancy unless absolutely indicated. Because Ceftriaxone is distributed into milk, the drug should be used with caution in nursing women.

Use in Children & Adolescent

See the dosage guideline.

Drug Interaction

a) **With Medicine:** No impairment of renal function or increased nephrotoxicity has been observed in man after simultaneous administration of ceftriaxone with diuretics, or with aminoglycosides. A possible disulfiram-like reaction may occur with alcohol. Other significant interactions: Ceftriaxone doesn't interfere with the protein binding of bilirubin. Simultaneous administration of probenecid doesn't alter the elimination of Ceftriaxone. Potentially useful interactions: Experimentally, in vivo, Ceftriaxone has been shown to enhance bacterial killing by human neutrophils.

b) **With Food & others:** There is no specific food-drug interaction. Using alcohol or tobacco with ceftriaxone may cause interactions to occur.

Overdose

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

Storage

Store below 30° C. protect from light & moisture. Use reconstituted solutions immediately. Reconstituted solutions are stable for 6 hours at room temperature and for 24 hours at 2-8°C. Keep all medicines out of reach of children.

Packing

Maxzon 250 mg IM Injection: Each box containing one vial 250 mg Ceftriaxone (as sterile Ceftriaxone Sodium USP) and 1 ampoule of 2 ml Lidocaine Hydrochloride USP 1 % solution. It also contains disposable syringe (5 ml), baby needle, alcohol pad and first aid bandage.

Maxzon 500 mg IM Injection: Each box containing one vial 500 mg Ceftriaxone (as sterile Ceftriaxone Sodium USP) and 1 ampoule of 2 ml Lidocaine Hydrochloride USP 1 % solution. It also contains disposable syringe (5 ml), baby needle, alcohol pad and first aid bandage.

Maxzon 1gm IV Injection: Each box containing one vial 1 gm Ceftriaxone (as sterile Ceftriaxone Sodium USP) and 1 ampoule of 10 ml water for injection USP. It also contains disposable syringe (10 ml), butterfly needle, alcohol pad and first aid bandage.

Maxzon 2gm IV Injection: Each box containing one vial 2 gm Ceftriaxone (as sterile Ceftriaxone Sodium USP) and 2 ampoules of 10 ml water for injection USP. It also contains disposable syringe (20 ml), butterfly needle, alcohol pad and first aid bandage.

Manufactured by
Apex Pharma Ltd.
Shafipur, Kaliakair, Gazipur, Bangladesh

for

ONE PHARMA LTD.

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Bogura, Bangladesh

