

MAXIZONE

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory Only
Abbreviated Prescribing information for MAXIZONE [Ceftriaxone Injection I.P. 500 mg and 1000 mg]

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

MECHANISM OF ACTION: Ceftriaxone inhibits bacterial cell wall synthesis following attachment to penicillin binding proteins (PBPs). This results in the interruption of cell wall (peptidoglycan) biosynthesis, which leads to bacterial cell lysis and death.

INDICATIONS It is indicated in treatment of UTI, lower respiratory tract infection, bacteraemia, septicaemia, meningitis, abdominal infection and infection caused by pseudomonas species.

DOSAGE AND ADMINISTRATION: The dose depends on the severity, susceptibility, site and type of infection and on the age and hepato-renal function of the patient.

CONTRAINDICATION: Hypersensitivity to the active substance, to any other cephalosporin or to any of the excipients. • History of severe hypersensitivity (e.g. anaphylactic reaction) 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 hyperbilirubinemia, jaundice, or who are hypoalbuminemia or acidotic because these are conditions in which bilirubin binding is likely to be impaired* Page 7 of 28 o 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. See information in the Summary of Product Characteristics of lidocaine, especially contraindications. • Ceftriaxone solutions containing lidocaine should never be administered intravenously.

WARNINGS & PRECAUTIONS: Ceftriaxone can cause serious hypersensitivity reactions, severe skin reactions, immune-mediated haemolytic anaemia, encephalopathy, and antibiotic-associated colitis, requiring immediate discontinuation if severe reactions occur. It must not be co-administered intravenously with calcium-containing solutions—especially in neonates—due to fatal precipitation risk and is contraindicated in neonates at risk of bilirubin encephalopathy. Long-term use requires blood count monitoring, and caution is needed in severe renal or hepatic impairment. Ceftriaxone may interfere with laboratory tests, has a limited antibacterial spectrum, can cause biliary or renal precipitation (sometimes leading to biliary stasis or pancreatitis), and may cause superinfections; benefits and risks should be assessed carefully, particularly in paediatric and elderly patients.

DRUG INTERACTIONS: Ceftriaxone must not be mixed or given simultaneously with calcium-containing intravenous solutions (e.g. Ringer's or Hartmann's) due to precipitation risk, especially in neonates, though in non-neonates sequential administration is allowed with thorough line flushing. Concomitant use may increase bleeding risk with

oral anticoagulants (requiring INR monitoring), may require renal and drug-level monitoring when used with aminoglycosides, and shows in-vitro antagonism with chloramphenicol of unclear clinical relevance. Ceftriaxone can cause false-positive Coombs', galactosaemia, and urine glucose tests, but shows no interaction with oral calcium products, no renal impairment with potent diuretics, and its elimination is not affected by probenecid.

ADVERSE REACTIONS: Eosinophilia, Leucopenia, Thrombocytopenia, Genital fungal infection, Pseudomembranous colitis, superinfection, anemia, coagulopathy, Anaphylactic shock Anaphylactic reaction Anaphylactoid reaction Hypersensitivity, Jarisch Herxheimer reaction, headache, dizziness, encephalopathy, convulsion, vertigo, bronchospasm, diarrhea, loose stools, nausea, vomiting, pancreatitis, stomatitis, glossitis, hepatic enzyme increased, gall bladder precipitation, Kernicterus, hepatitis, Stevens Johnson Syndrome Toxic epidermal necrolysis Erythema multiforme Acute generalized exanthematous pustulosis drug reaction with eosinophilia and systemic symptoms (DRESS), rash, pruritus, urticaria, Hematuria, Glycosuria, Oliguria Renal precipitation (reversible), Phlebitis Injection site pain Pyrexia, Oedema, Chills, Blood creatinine increased, Coombs test false positive, Galactosemic test false positive, Non enzymatic methods for glucose determination false positive.

MARKETED BY:



TORRENT PHARMACEUTICALS LTD.

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(Additional information is available on request)