Ceftron®

Ceftriaxone

COMPOSITION

Ceftron® 250 mg IM/IV injection:
Each vial contains dry substance equivalent to 250 mg Ceftriaxone (as sterile Ceftriaxone Sodium USP) accompanied by an ampoule of 5 ml sterilised Water for Injections BP (Sterile).
Ceftron® 500 mg IM/IV injection:
Each vial contains dry substance equivalent to 500 mg Ceftriaxone (as sterile Ceftriaxone Sodium USP) accompanied by an ampoule of 5 ml sterilised Water for Injections BP (Sterile).
Ceftron® 1gm IM/IV injection:
Each vial contains dry substance equivalent to 1 gm Ceftriaxone (as sterile Ceftriaxone Sodium USP) accompanied by an ampoule of 10 ml sterilised Water for Injections BP (Sterile).
Ceftron® 250 mg IM injection:
Each vial contains Ceftriaxone 250 mg (as sterile Ceftriaxone Sodium USP) accompanied by 2 ml Lidocaine HCl USP 1% Injection (Sterile).
Ceftron® 500 mg IM injection:
Each vial contains Ceftriaxone 500 mg (as sterile Ceftriaxone Sodium USP) accompanied by an ampoule of 2 ml Lidocaine HCl USP 1% Injection (Sterile).
Ceftron® 1gm IM injection:
Each vial contains Ceftriaxone 1 gm (as sterile Ceftriaxone Sodium USP) accompanied by an ampoule of 3.5 ml Lidocaine HCl USP 1% Injection (Sterile).
Ceftron® 250 mg IV injection:
Each vial contains dry substance equivalent to 250 mg Ceftriaxone (as sterile Ceftriaxone Sodium USP) accompanied by an ampoule of 5 ml sterilised Water for Injections BP (Sterile).
Ceftron® 500 mg IV injection:
Each vial contains dry substance equivalent to 500 mg Ceftriaxone (as sterile Ceftriaxone Sodium USP) accompanied by an ampoule of 5 ml sterilised Water for Injections BP (Sterile).
Ceftron® 1gm IV injection:
Each vial contains Ceftriaxone 1 gm (as sterile Ceftriaxone Sodium USP) accompanied by an ampoule of 10 ml sterilised Water for Injections BP (Sterile).
Ceftron® 2 gm IV injection:
Each vial contains Ceftriaxone 2 gm (as sterile Ceftriaxone Sodium USP) accompanied by two ampoules of 10 ml sterilised Water for Injections BP.

PHARMACOLOGY

Ceftron® (Ceftriaxone) is a third generation broad spectrum parenteral cephalosporin antibiotic. It has potent bactericidal activity against a wide range of Gram-positive and, especially, Gram-negative organisms. The spectrum of activity includes both aerobic and some anaerobic species. **Ceftron®** like other cephalosporins and penicillins, kills bacteria by interfering with the synthesis of the bacterial cell wall. **Ceftron®** has a high degree of stability in the presence of beta lactamases, both penicillinases and cephalosporinases, of gram-positive and gram-negative bacteria. **Ceftron®** (Ceftriaxone) is not absorbed after oral administration and must be given parenterally. Following IM or IV administration, ceftriaxone is widely distributed into body tissues and fluids including gallbladder, lungs, bone, bile, prostate adenoma tissue, uterine tissue, atrial appendage, sputum, tears, and pleural, peritoneal, synovial, ascitic, and blister fluids. **Ceftron®** (Ceftriaxone) is eliminated mainly as unchanged ceftriaxone, approximately 60% of the dose being excreted in the urine (almost
exclusively by glomerular filtration) and the remainder via the biliary and intestinal tracts.
The mean elimination half-life of **Ceftron®** is generally about 6 to 9 hours in healthy adults following single or multiple intravenous, intramuscular or subcutaneous injection. Thus **Ceftron®** (Ceftriaxone) has much longer elimination half-life than any of the other currently available cephalosporins. **Ceftron®** 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

Ceftron® is indicated for the treatment of the following major infections
when caused by susceptible organisms:
1. Renal and urinary tract infections
2. Lower respiratory tract infections, particularly pneumonia
3. Gonococcal infections
4. Skin and soft tissue, bone and joint infections
5. Bacterial meningitis
6. Serious bacterial infections e.g. septicemia
7. ENT infections
8. Infections in cancer patients
9. Prevention of postoperative infection
10. Perioperative prophylaxis of infections associated with surgery
11. Typhoid fever

DOSAGE AND ADMINISTRATION

Ceftron® (ceftriaxone) can be administered either intravenously or intramuscularly. When reconstituted for intramuscular or intravenous injection, the white to yellowish-orange crystalline powder gives a pale yellow to amber solution.
Adults: The usual adult daily dose is 1-2 g 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 4g. For preoperative use (surgical prophylaxis), a single dose of 1 gm administered intravenously 0.5-2 hours before surgery is recommended. In elderly patients, the dosages do not require modification provided that renal and hepatic functions are satisfactory. In patients with impaired renal function, there is no need to reduce the dosage of **Ceftron®** provided liver function is intact. In patients with liver damage, there is no need for the dosage to be reduced provided renal function is intact. Gonorrhea: For the treatment of gonorrhea (penicillinase producing and non-penicillinase producing strains), a single intramuscular dose of 250 mg is recommended.

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.

RECONSTITUTION OF INJECTION BEFORE ADMINISTRATION :
Please follow the below-mentioned guideline for reconstitution of Ceftron® IM / IV Injection with supplied Water for Injection (WFI) BP.

Strength	Volume of WFI for IV administration	Amount of WFI for IM administration
250 mg	2.4 ml	0.9 ml
500 mg	4.8 ml	1.8 ml
1 gm	9.6 ml	3.6 ml
2 gm	19.2 ml	7.2 ml

* WFI : Water for injection.

CONTRAINDICATION AND PRECAUTION

Ceftriaxone should not be given to patients with a history of hypersensitivity to cephalosporin antibiotics. It is contraindicated in premature infants during the first 6 weeks of life. Its safety in human pregnancy has not been established. Therefore it should not be used in pregnancy unless absolutely indicated. Only minimal amount of Ceftriaxone has excreted in breast milk, so mothers receiving Ceftriaxone should not breast-feed. The stated dosage should not be exceeded. In severe renal impairment accompanied by hepatic insufficiency, dosage reduction is required.

SIDE EFFECT

Ceftriaxone is generally well tolerated. A few side-effects such as: 1. Gastrointestinal effects include diarrhea, nausea and vomiting, stomatitis and glossitis 2. Cutaneous reactions include rash, pruritus, urticaria, edema & erythema multiforme 3. Hematological reactions include eosinophilia, thrombocytosis, leukopenia, and neutropenia 4. Hepatic reactions include elevations of SGOT or SGPT, bilirubinemia 5. 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.

DRUG INTERACTION

Potentially hazardous interactions: 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.

USE IN PREGNANCY AND 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.

STORAGE CONDITION

Store below 25ºC, protected from light and moisture. Freshly reconstituted solutions is always recommended. Reconstituted solution can be stored up to 6 hours at room temperature (up to 25ºC and indoor light) and for 24 hours in refrigerator (at 2º-8ºC).

HOW SUPPLIED

Ceftron® is supplied as a sterile crystalline powder in glass vials.
Ceftron® 250 mg IM/IV injection : Pack of 1 vial containing 250 mg Ceftriaxone (as sterile Ceftriaxone Sodium USP) accompanied by one ampoule of 5 ml sterilised Water for Injections BP.
Ceftron® 500 mg IM/IV injection : Pack of 1 vial containing 500 mg Ceftriaxone (as sterile Ceftriaxone Sodium USP) accompanied by one ampoule of 5 ml sterilised Water for Injections BP.
Ceftron® 1 gm IM/IV injection : Pack of 1 vial containing 1 gm Ceftriaxone (as sterile Ceftriaxone Sodium USP) accompanied by one ampoule of 10 ml sterilised Water for Injections BP.
Ceftron® 250 mg IM injection : Pack of 1 vial containing 250 mg Ceftriaxone (as sterile Ceftriaxone Sodium USP) accompanied by one ampoule of 2 ml Lidocaine HCl Injection USP 1% for IM injection.
Ceftron® 500 mg IM injection : Pack of 1 vial containing 500 mg Ceftriaxone (as sterile Ceftriaxone Sodium USP) accompanied by one ampoule of 2 ml Lidocaine HCl Injection USP 1% for IM injection.
Ceftron® 1 gm IM injection : Pack of 1 vial containing 1 gm Ceftriaxone (as sterile Ceftriaxone Sodium USP) accompanied by one ampoule of 3.5 ml of Lidocaine HCl 1% injection for IM injection.
Ceftron® 250 mg IV injection : Pack of 1 vial containing 250 mg Ceftriaxone (as sterile Ceftriaxone Sodium USP) accompanied by one ampoule of 5 ml sterilised Water for Injections BP.
Ceftron® 500 mg IV injection : Pack of 1 vial containing 500 mg Ceftriaxone (as sterile Ceftriaxone Sodium USP) accompanied by one ampoule of 5 ml sterilised Water for Injections BP.
Ceftron® 1 gm IV injection : Pack of 1 vial containing 1 gm Ceftriaxone (as sterile Ceftriaxone Sodium USP) accompanied by one ampoule of 10 ml sterilised Water for Injections BP.
Ceftron® 2 gm IV injection : Pack of 1 vial containing 2 gm Ceftriaxone (as sterile Ceftriaxone Sodium USP) accompanied by two ampoules of 10 ml sterilised Water for Injections BP.

SQUARE