hovid

Ceftriaxone

Hoftrex

Powder for Injection (IV/IM)
Antibacterial

Formulation

hovid-Hoftrex 1 g : Each vial contains Ceftriaxone Sodium U.S.P. equivalent to Ceftriaxone 1 g

Description

Almost white or yellowish, crystalline, slightly hygroscopic powder.

Pharmacology

Ceftriaxone is a broad-spectrum third-generation cephalosporin antibiotic for intravenous or intramuscular administration. It binds to penicillin-binding proteins located in bacterial cytoplasmic membranes to inhibit bacterial septum and cell wall synthesis. By acylation of membrane-bound transpeptidase enzymes, ceftriaxone prevents the cross-linkage of peptidoglycan chains, which is necessary for bacterial cell wall strength and rigidity. Furthermore, cell division and growth are inhibited, as well as the elongation of susceptible bacteria, frequently causing lysis. Ceftriaxone has excellent activity against a wide spectrum of gram-negative and gram-positive bacteria. It is highly stable against hydrolysis by most beta-lactamases (penicillinases and cephalosporinases), produced by gram-negative and gram-positive bacteria.

Pharmacokinetics

Following the IM administration of ceftriaxone in a healthy adult, the drug appears to be completely absorbed. Peak serum concentrations are attained in between 2 to 3 hours post dosing. Ceftriaxone is reversibly bound to human plasma proteins and widely distributed in body tissues and fluids. It crosses both inflamed and non-inflamed meninges, and achieves therapeutic concentrations in the cerebrospinal fluid (CSF). Ceftriaxone crosses the placenta and low concentrations have been detected in breast milk. High concentrations are found in bile. Plasma portein binding is about 85-95%. The plasma half-life of ceftriaxone is not dependent on the dose and varies between 6 and 9 hours. About 40 to 65% of a dose of ceftriaxone is excreted unchanged in the urine while the remainder is excreted in the bile and found ultimately in the faeces as an unchanged drug along with several microbiologically inactive compounds.

Indications

For treatment of the following infections caused by susceptible organisms:

- Bone and joint infections
- Uncomplicated gonorrhoea
- Intra-abdominal infections
- Lyme disease
- Meningitis
- Otitis media
- Female pelvic infections
- Respiratory tract infections, particularly bacterial pneumonia
- Bacterial septicaemia
- Skin and soft tissue infections
- Bacterial urinary tract infections

For prophylaxis of:
Post operative infections caused by susceptible organisms throughout the course of the surgical procedures.

Contraindications

- This medication should not be used by patients with known allergy to penicillins, penicillin derivatives, penicillamine, or cephalosporins.
- Risks and benefits of the use of ceftriaxone should be weighed in patients with colitis, gastrointestinal disease, regional enteritis or antibiotic-associated colitis as pseudomembranous colitis ranging from mild to life-threatening may occur.

Precautions

- Patients on dialysis may require dosage adjustment due to reduced elimination rate.
- Use with caution in patients with history of bleeding disorders, as cephalosporins may cause hypoprothrombinemia.

Use in pregnancy and lactation

Ceftriaxone crosses the placenta. Adequate and well-controlled studies in humans have not been conducted. Ceftriaxone is excreted in breast milk, usually in low concentrations. Cautions should be exercised when ceftriaxone is administered.

Main Side/Adverse Effects

Ceftriaxone is generally well tolerated. Eosinophilia is the most frequent adverse effect. GI disturbance especially diarrhoea may occur. Lesser reported GI effects include nausea, vomiting, dysgeusia and pseudomembranous colitis. Biliary sludge or pseudolithiasis due to a precipitate of calcium ceftriaxone has been seen occasionally in patients receiving ceftriaxone. Elevations of liver enzymes (SGOT and SGPT) and transient elevations of BUN have been observed. Hypersensitivity reactions (fever, swelling, itching, rash, or redness), haematological

changes (leucopenia, neutropenia, thrombocytopenia, agranulocytosis, aplastic anemia or hemolytic anemia), skin reactions (erythema multiforme or Stevens-Johnson syndrome) and thrombophlebitis (IV administration) are incidences that have been reported.

Drug Interactions

- Concurrent use of anticoagulant with ceftriaxone may increase the risk of bleeding as ceftriaxone can inhibit vitamin K synthesis by suppressing gut flora.
- Ceftriaxone has the potential to cause a disulfiram-like reaction when taken with alcohol.
- The admixture of ceftriaxone and vancomycin and fluconazole are physically incompatible.
- The admixture of ceftriaxone with other medications, including pentamidine isethionate, or with labetalol hydrochloride is not recommended.
- The admixture of beta-lactam antibacterials (penicillins and cephalosporins) and aminoglycosides may result in substantial mutual inactivation. If they are administered concurrently, they should be administered at separate sites.

Overdose

There is no known specific antidote to ceftriaxone. Drug concentration would not be reduced by hemodialysis or peritoneal dialysis. Treatment of overdosage is generally symptomatic and supportive.

Dosage and Administration

Usual adult and adolescent dose:
For perioperative prophylaxis: IV, 1 g (base) one-half to two hours prior to the start of surgery.
For all other indications: IM or IV, 1 to 2 g every twenty-four hours; or 1 g every twelve hours.
Not exceeding 4 g per day.

Usual pediatric dose:
For meningitis: IM or IV, initial dose of 100 mg (base) per kg of body weight, up to 4 g, followed by 100 mg per kg of body weight every twenty-four hours, or 50 mg per kg of body weight every twelve hours, up to 4 g per day, for seven to fourteen days.
For otitis media: IM, 50 mg (base) per kg of body weight, up to 1 g, as a single dose.
For skin and soft tissue infections: IM or IV, 50 to 75 mg (base) per kg of body weight every twenty-four hours, or 25 to 37.5 mg per kg of body weight every twelve hours, up to 2 g per day.
For all other serious infections: IM or IV, 25 to 37.5 mg (base) per kg of body weight every twelve hours, up to 2 g per day.

DIRECTIONS FOR USE
IV administration. Reconstitute as below:

Vial Dosage Size	Amount of Sterile Water for Injection to be Added
1 g	9.6 ml

IM administration. Reconstitute as below:

Vial Dosage Size	Amount of Sterile Water for Injection to be Added
1 g	3.6 ml

COMPATIBILITY AND STABILITY
Reconstituted Ceftriaxone Sodium for injection for IM administration is stable for 24 hours at 25°C and for 3 days if refrigerated at 2-4°C. Reconstituted Ceftriaxone Sodium for Injection for IV administration is stable for 2 days at 25°C and for 10 days if refrigerated at 2-4°C. Frozen solution should be thawed at room temperature before use and discarded after use. Do no re-freeze.

Note: The information given here is limited. For further information, consult your doctor or pharmacist.

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph

Caution	: Food, Drugs, Devices & Cosmetics Act prohibits dispensing without prescription
Storage condition	: Store at temperature not exceeding 30°C. Protect from light and moisture.
Availability	: 1 pack contains 1 g vial + 1 ampoule water for injection
Registration No.	: DR-XY41415
Date of Renewal of the Authorization	: November 2017
Manufactured for	: HOVID Bhd., 121, Jalan Tunku Abdul Rahman, 30010 Ipoh, Malaysia. By: Nectar Lifesciences Limited (Unit VI), Village Bhatolikalan - Adjoining Jharmjri EPIP, P.O. Barotiwala, Tehsil-Nalagarh District Solan, Himachal Pradesh, 173205, India
Imported & Distributed by	: HOVID Inc., Unit B, 7th Floor, Karina Building, 33 Shaw Boulevard, Pasig City, Philippines.
Information Date	: July 2018