SUMMARY OF PRODUCT CHARACTERISTICS

1-Name of the Medicinal Product:

1.1 Product Name
Hovid Hoftrex 1 g Injection

1.2 Strength
1g/vial

1.3 Pharmaceutical Dosage Form
Powder for Injection

2-Quality and Quantitative Composition:

2.1 Qualitative Declaration

1. Ceftriaxone Sodium

2.2 Quantitative Declaration

No	Name of Ingredient	Vial/g
1	Ceftriaxone Sodium equivalent to Ceftriaxone	1g

3-Pharmaceutical Form:

Powder for Injection
White to yellowish-orange crystalline powder filled in clear, transparent, 10ml glass vial with grey coloured bromo butyl rubber stopper and coloured flip-off seal

4-Clinical Particulars:

4.1 Therapeutic indications
For treatment f 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.

4.2 Posology and method of administration

Usual adult and adolescent dose:
For uncomplicated gonorrhoea: IM, 0.25 g (base) as a single 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 0.5 g to 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. Constitute as below:

Vial Dosage Size	Amount of Sterile Water for Injection
0.25 g	2.4 ml
0.5 g	4.8 ml
1 g	9.6 ml

IM administration. Constitute as below:

Vial Dosage Size	Amount of Sterile Water for Injection
0.25 g	0.9 ml
0.5 g	1.8 ml
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 4˚C. Reconstituted Ceftriaxone Sodium for Injection for IV administration is stable for 3 days at 25˚C and for 10 days if refrigerated at 4˚C. Frozen solution should be thawed at room temperature before use and discarded after use. Do not re-freeze.

4.3 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.

4.4 Special warning and precautions for use

- 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.

4.5 Interaction with other medicinal products and other forms of Interactions

- Concurrent use of anticoagulant with ceftriaxone may increase the risk of bleeding as ceftriaxoxe 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.

4.6 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.

4.7 Effects on ability to drive and use machine

NOT APPLICABLE.

4.8 Undesirable 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 (leukopenia, 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.

4.9 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.

5-Pharmacological Properties:

5.1 Pharmacodynamic Properties

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. Ceftraixone 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 bacterial.

5.2 Pharmacokinetic properties

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 protein 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.

5.3 Preclinical safety data

Not available

6-Pharmaceutical Particulars:

6.1 List of excipients

No excipient in the formulation

6.2 Incompatibilities

NOT APPLICABLE

6.3 Shelf life

3 years from date of manufacture.

6.4 Special precautions for storage

Store below 30°C. Protect from light and moisture.

6.5 Nature and contents of container

Vials	
Name of the Component	10 ml Moulded clear Glass vial Type III
Material of Construction	Type III, moulded clear glass vials are mad borosilicate, which has a highly resistant c releases the least amount of alkali.
Size	10 ml
Neck Size	20 mm
Rubber Stopper	
Name of the Component	Stopper, grey bromo butyl rubber, 20 mm
Material of Construction	Grey color Bromo Butyl Rubber
Size	20 mm
Seals	
Name of the Component	20 mm Aluminium seal with royal blue col

6.6 Special precaution for disposal

Not Applicable

7- Registrant:

Marketing Authorization Holder

Name : HOVID Bhd.
Address : 121, Jalan Tunku Abdul Rahman,
(Jalan Kuala Kangsar)
30010 Ipoh, Perak, Malaysia

Manufacturer and manufacturing site

Name : Nectar Lifesciences Limited (Unit-VI)
Address : No. Vill. Bhatolikalan (Adjoining Jharmajri, EPIP) P.O. Barotiwala, Tehsil Nalagarh Distt. Solan [H.P.], India.

8-Date of revision of the text:

February 2016

9-Dosimetry (If applicable):

Not Applicable

10-Instruction for preparation of Radiopharmaceuticals (If Applicable):

Not Applicable