1.6 Product Information

1.6.1Prescribing information (Summary of Product Characteristics)

(1) Name of the medicinal product

Ceftriaxone sodium for injection

(2)ATC and forensic classification

ATC code: J01DD04; β-lactam antibacterial, prescription

(3) Qualitative and quantitative composition

Components	Unit dose	Function
Ceftriaxone sodium	Equivalent to Ceftriaxone 1.0g/vial	Active ingredient

(4) Pharmaceutical form

Powder for injection

(5) Clinical particulars

(5.1) Therapeutic indications

INDICATIONS:

Infections caused by pathogens sensitive to ceftriaxone such as

Sepsis

Mining it is in neonates infants

Preoperative prophylaxes is of infections.

Renalan durinary tract infections

Respiratory tract infections, particularly pneumonia, and ear, nose and throat infections.

Infection soft the bones, joints, soft tissue, skin and wounds

Abdominal infections (peritonitis, infections of the biliary tract).

Uncomplicated gonorrhea.

(5.2)Contraindications

Allergy to cephalosporins, in patients hypersensitive to penicillin, the possibility of allergic cross reactions should be borne in mind.

(5.3) Special warnings and precautions for use

Hypersensitivity reactions to cephalosporins, penicillins or other medicines. About10% of penicillin-sensitive patients may also be allergic to cephalosporins although the true incidence is uncertain.

(5.4) Drug Interactions

No impairment of renal function has been observed after concurrent administration of large doses of Ceftriaxone and potent diuretics (e.g. furosemide). There is no evidence that Ceftriaxone increases renal toxicity of aminoglycosides. No effect similar to that of disulfiram has been demonstrated

after administration of alcohol with Ceftriaxone.

Ceftriaxone does not contain an N-methyl-thiotetrazole moiety associated with possible ethanol intolerance and bleeding problems. The elimination of Ceftriaxone is not altered by probenecid.

In an in vitro study antagonistic effects have been observed with the combination of chloramphenicol and Ceftriaxone.

There may be antagonism between Ceftriaxone and bacteriostatic antibacterial agents. Ceftriaxone may interfere with the Jaffe method of measuring creatinine concentrations and may produce falsely high values; this should be borne in mind when measuring renal function.

In patients treated with ceftriaxone the Combs' test may become false positive. Ceftriaxone may result in false positive tests for galactosemia.

Likewise, non-enzymatic methods for the glucose determination in urine may give false positive results. For this reason urine glucose determination during the rap with Ceftriaxone should be done enzymatically.

(5.5) Pregnancy and lactation

Safety in human pregnancy has not been established. As ceftriaxone is excreted in the breast milk at low concentrations, caution is advised in nursing mothers.

(5.6) Effects on ability to drive and machines

During treatment with ceftriaxone, undesirable effects may occur (e.g. dizziness), which may influence the ability to drive and use machines. Patients should be cautious when driving or operating machinery.

(5.7) Undesirable effects

The most frequently reported adverse reactions for ceftriaxone are eosinophilia, leucopenia, thrombocytopenia, diarrhea, rash, and hepatic enzymes increased.

(5.8) Overdose

In the case of overdose, plasma concentration would not be reduced by hemodialysis or peritoneal dialysis. Treatment is supportive and symptomatic.

(6) Pharmacological properties

(6.1) Pharmacodynamics properties

Mechanism of action

Ceftriaxone is a broad-spectrum cephalosporin with a long plasma elimination half-life of approximately 8 hours in normal adults.

Antimicrobial Profile

(In vitro sensitivity does not necessarily imply in vivo efficacy).The in vitro spectrum of activity of ceftriaxone encompasses:

(a) Gram-positive organisms:

Streptococcus pneumoniae, Streptococcus Group A (including Streptococcus pyogenes), Streptococcus Group B (including Streptococcus agalactiae), Streptococcus viridians, Streptococcus bovid (Group D), Staphylococcus aureus (methicillin sensitive). Peptostrept ococcus sp .and Clostridium sp.

Note: Methicillin-resistant Staphylococcus spp. are resistant to ceftriaxone. Enterococcus facials, Enterococcus fascism and Listeria monocytogenes are resistant.

(b) Gram-negative organisms:

Hemophilic influenza (including ampicillin-resistant strains), Hemophilic parainfluenza, Neisseria meningitidis, Neisseria gonorrhoeae (including penicillin-resistant strains), Escherichia coli, Klebsiella sp**, Enterobacter sp*. Serratia marcescens, Citrobacter sp., Proteus mirabilis, Indole-positive Proteus (including Morganella morganii), Salmonella sp. Shigella sp., Yersinia pestis and Treponema pallidum (in animal experiments).

*Some isolates of these species are resistant to ceftriaxone, due to the production of the chromosomally encoded beta-lactamases.

**Some isolates of these species are resistant due to production of extended spectrum plasmid mediated beta-lactamase.

(c) Organisms which are only pat ally sensitive to ceftriaxone in vitro.

Staphylococcus epidermidis, Pseudomonas aeruginosa, Acinetobacter sp. and Bacteroides sp Ceftriaxone is stable in relation to the majority of beta-lactamases.

The following organisms are resistant:

Ureaplasma urealyticum, Mycoplasma sp., Mycobacterium sp.Fungi.

It is essential to note that recommended media (free from inhibitory substances especially thymidine and thymine) and methods must be used for satisfactory sensitivity testing

(6.2) Pharmacokinetic properties

Ceftriaxone is not absorbed after oral administration. But it is completely absorbed following intramuscular (IM) administration with peak levels occurring 2-4 hours after the dose. Ceftriaxone is reversibility bound to plasma proteins with 95% at plasma concentrations of less than 25 mcg/ml and 85% at 300 mcg/ml. Binding is less in neonates and children. Ceftriaxone penetrates well into most tissues and body fluids including CSF (with inflamed or non-inflamed meninges),sputum, pleural and peritoneal fluids, ascetic fluids, tears, blister fluid, bile, gallbladder wall, bone myometrium, fallopian tubes, prostrate, nasal mucosa, tonsil, middle ear mucosa and synovial fluid. Ceftriaxone is the first systemic cephalosporin to penetrate adequately into vitreous humor. Ceftriaxone is not metabolized in the body. 33 to 67% of the ceftriaxone is excreted unchanged in

the urine. The rest is secreted into the bile and ultimately excreted in the faces as inactive compounds.

(6.3) Preclinical safety data

There is evidence from animal studies that high doses of ceftriaxone calcium salt led to formation of concernments and precipitates in the gallbladder of dogs and monkeys, which proved to be reversible. Animal studies produced no evidence of toxicity to reproduction and genotoxicity. Carcinogenicity studies on ceftriaxone were not conducted.

(7) Pharmaceutical particulars

(7.1) Incompatibilities

Not applicable.

(7.2) Shelf life

3 years

(7.3) Special precautions for storage

Store in a dry place below 30℃. Protect from light.

(7.4) Nature and contents of container

Colourless Type III glass vial closed with a bromobutyl rubber stopper and sealed with an aluminium cap.

(7.5) Special precautions for disposal

Use as directed by a physician.