SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

MONOTAX 1GM

Ceftriaxone for Injection USP 1gm

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance Quantity

Each vial contains:

Ceftriaxone Sodium USP

Equivalent to Ceftriaxone 1 gm

For full list excipients, see section 6.1

3. PHARMACEUTICAL FORM

Powder for solution for injection or infusion

A white to yellowish-orange crystalline powder, filled in a colourless glass vial.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

- Lower Respiratory Tract Infections.
- Skin and Skin Structure Infections.
- Urinary Tract Infections (complicated and uncomplicated).
- Uncomplicated Gonorrhoea-Cervical, Urethral and Rectal.
- Pelvic Inflammatory Diseases.
- Bacterial Septicemia.
- Bone and Joint Infections
- Meningitis.
- Surgical Prophylaxis.

A single dose of Ceftriaxone preoperatively may reduce chances of postoperative infections

4.2 Posology and method of administration

The usual adult dose is 1-2 gm o.d./b.d. Total daily dose should not exceed 4 gm.
In infants and young children, the recommended daily dose is 50-75 mg/kg body weight given once-a-day or in two divided doses, the total daily dose should not exceed 2 gm. For the treatment of meningitis in children a dose of 100 mg/kg daily in two divided doses, sometimes with a loading dose of 75 mg/kg may be given. In premature babies/neonates the recommended daily dose is less than 50 mg/kg.

For preoperative use (surgical prophylaxis) a single dose of 1 gm, given ½ to 2 hours before surgery is recommended. For the treatment of uncomplicated gonorrhoea or cystitis, a single intramuscular dose of 250 - 500 mg is recommended.
For strep, pyogenes infections 10 day regimen is required.
No dosage adjustment is necessary for patients with impaired renal or hepatic function; however, blood levels should be monitored in patients with severe renal impairment (eg. dialysis patients) and in patients with both renal and hepatic dysfunctions.

4.3 Contraindications

Ceftriaxone is contraindicated in patients with known allergy to Cephalosporin group of antibiotics.

4.4 Special warnings and precautions for use

WARNING:
This product should be given cautiously to Penicillin sensitive patients. Antibiotics should be given cautiously to patients with any kind of allergy, particularly to drugs. Serious hypersensitivity reactions may require use of subcutaneous epinephrine and other emergency measures. Pseudomembraneous colitis has been reported with use of Cephalosporins and other broad spectrum antibiotics. Therefore, it is important to consider its diagnostis in patients who develop diarrhoea in association with antibiotic use. Treatment with broad spectrum antibiotics can alter normal flora of colon and promote growth of Clostridia.
PRECAUTIONS:
In renal failure no adjustment may be necessary but serum levels should be monitored periodically and the dosage reduced if required. Dosage adjustment is similarly not essential in hepatic failure; but in patients with both hepatic and significant renal malfunction blood levels should be monitored. Ceftriaxone doses should not exceed 2 gm/day without close serum monitoring. Rarely, alterations in prothrombin time have occurred and may require co-administration of vitamin K (10 mg weekly).
Prolonged use may cause overgrowth of non-susceptible organisms and cause superinfections. Administer with caution to patients with history of G. I. diseases, especially, colitis.

4.5 Interaction with other medicinal products and other forms of interaction

Ceftriaxone solutions should not be mixed with other antimicrobial agents.

4.6 Fertility, pregnancy and lactation

PREGNANCY:

No evidence of embryotoxicity, fetotoxicity or teratoginicity seen upto 20 times the usual human dose given to mice. As there are no adequate trials in pregnant women, administer only if clearly necessary.

NURSING MOTHERS:

As low concentration are excreted in milk, caution should be exercised.

4.7 Effects on ability to drive and use 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.

4.8 Undesirable effects

The most frequently reported adverse reactions for ceftriaxone are eosinophilia, leucopenia, thrombocytopenia, diarrhoea, rash, and hepatic enzymes increased.
Data to determine the frequency of ceftriaxone ADRs was derived from clinical trials. The following convention has been used for the classification of frequency:
Very common (≥ 1/10)
Common (≥ 1/100 - < 1/10)
Uncommon (≥ 1/1000 - < 1/100)
Rare (≥ 1/10000 - < 1/1000)
Not known (cannot be estimated from the available data)

Class	**Common**	**Uncommon**	**Rare**	**Not Known** [a]
Infections and infestations		Genital fungal infection	Pseudo membranous colitis[b]	Superinfection[b]
Blood and lymphatic system disorders	Eosinophilia Leucopenia Thrombocytopenia	Granulocytopenia Anaemia Coagulopathy		Haemolytic anaemia[b] Agranulocytosis
Immune system disorders				Anaphylactic shock Anaphylactic reaction Anaphylactoid reaction Hypersensitivity[b]
Nervous system disorders		Headache Dizziness		Convulsion
Ear and labyrinth disorders				Vertigo
Respiratory, thoracic and mediastinal disorders			Bronchospasm	
Gastrointestinal disorders	Diarrhoea[b] Loose stools	Nausea Vomiting		Pancreatitis[b] Stomatitis Glossitis
Hepatobiliary disorders	Hepatic enzyme increased			Gall bladder precipitation[b] Kernicterus

Skin and subcutaneous tissue disorders	Rash	Pruritus	Urticaria	Stevens Johnson Syndrome[b] Toxic epidermal necrolysis[b] Erythema multiforme Acute generalised exanthematous pustulosis
Renal and urinary disorders			Haematuria Glycosuria	Oliguria Renal precipitation (reversible)
General disorders and administration site conditions		Phlebitis Injection site pain Pyrexia	Oedema Chills	
Investigations		Blood creatinine increased		Coombs test false positive[b] Galactosaemia test false positive[b] Non enzymatic methods for glucose determination false positive[b]

[a]Based on post-marketing reports. Since these reactions are reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency which is therefore categorised as not known.
[b] See section 4.4

Infections and infestations

Reports of diarrhoea following the use of ceftriaxone may be associated with Clostridium difficile. Appropriate fluid and electrolyte management should be instituted.

Ceftriaxone-calcium salt precipitation

Rarely, severe, and in some cases, fatal, adverse reactions have been reported in pre- term and full-term neonates (aged < 28 days) who had been treated with intravenous ceftriaxone and calcium. Precipitations of ceftriaxone-calcium salt have been observed in lung and kidneys post-mortem. The high risk of precipitation in neonates is a result of their low blood volume and the longer half-life of ceftriaxone compared with adults.

Cases of renal precipitation have been reported, primarily in children older than 3 years of age and who have been treated with either high daily doses (e.g. ≥ 80 mg/kg/day) or total doses exceeding 10 grams and who presented with other risk factors (e.g. fluid restrictions or confinement to bed). The risk of precipitate formation is increased in immobilized or dehydrated patients. This event may be symptomatic or asymptomatic, may lead to renal insufficiency and anuria, and is reversible upon discontinuation of ceftriaxone.

Precipitation of ceftriaxone calcium salt in the gallbladder has been observed, primarily in patients treated with doses higher than the recommended standard dose. In children, prospective studies have shown a variable incidence of precipitation with intravenous application - above 30 % in some studies. The incidence appears to be lower with slow infusion (20 - 30 minutes). This effect is usually asymptomatic, but the precipitations have been accompanied by clinical symptoms such as pain, nausea and vomiting in rare cases. Symptomatic treatment is recommended in these cases.

Precipitation is usually reversible upon discontinuation of ceftriaxone.

'Reporting of suspected adverse reactions
Healthcare professionals are requested to report any suspected adverse reactions via the Pharmacy and Poisons Reporting System (PVERS) https://pv.pharmacyboardkenya.org

4.9 Overdose

In overdose, the symptoms of nausea, vomiting and diarrhoea can occur. Ceftriaxone concentrations cannot be reduced by haemodialysis or peritoneal dialysis. There is no specific antidote. Treatment is symptomatic.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Ceftriaxone has a broad spectrum activity in vitro which includes Gram-positive and Gram-negative aerobic and some anaerobic bacteria. Ceftriaxone has a high degree of stability in presence of beta-lactamases, both penicillinases and cephalosporinases of Gram-negative and Gram-positive bacteria.

Ceftriaxone usually shows good in vitro activity against the following organisms.

GRAM-NEGATIVE AEROBES:
Enterobacter aerogenes
Enterobacter cloacae
E.Coli
H.influenzae (including Ampicillin resistant strains)
H.parainfluenzae
Klebsiella spp. (including K.pneumoniae)
N.gonorrhoeae (including pencillinase and non- pencillinase producing strains)
N.meningitidis
P.mirabilis
P.vulgaris
Morganella morganil
Serratia marcescens
Citrobacter freundii

Citrobacter diversus
Providencia spp.
Salmonella spp.
Shigella spp.
Acinetobacter calcoaceticus
Ceftriaxone is also active against many strains of Ps.aeruginosa.

GRAM-POSITIVE AEROBES:
Staphylococcus aureus (including penicillinase-producting strains)
Staphylococcus epidermidis
(Note: Methicillin resistant Staphylococci are resistant to all Cephalosporins including Ceftriaxone)
Staphylococcus pyogenes (Group A Beta-hemolytic)
Staphylococcus agalactiae (Group B Staphylococci)
Staphylococcus pneumoniae.

ANAEROBES:
Bacteroides spp.
Clostridia (but most Cl. difficile strains are resistant)

5.2 Pharmacokinetic properties

ABSORPTION:

Bioavailability of Ceftriaxone after intramuscular administration is 100%. On intravenous administration, Ceftriaxone rapidly diffuses into the tissue fluid, where if it is given in the recommended dosage range bactericidal concentrations lasting 24 hours are attained.

DISTRIBUTION:

Apparent volume of distribution of Ceftriaxone is 5.78 – 13.5 L.
Ceftriaxone is reversibly bound to plasma proteins. Concentrations of Ceftriaxone inhibitory for most Gram-negative bacteria are attained in the meninges, in purulent sputum and in synovial, prostatic and pleural fluid. Ceftriaxone also reaches high concentrations in the blister and peritoneal fluid, bone, myometrium endometrium and salpings tissue.
Ceftriaxone is excreted in breast milk (AUC in milk is 3-4% of AUC in serum). High concentrations are also seen in bile. Elimination half life of Ceftriaxone is 6-9 hours.

EXCRETION:

Major excretory pathway is urine (40-60%) by glomerular filteration. Some amount is eliminated via bile (11-65%). In infants and children Elimination half-life in neonates is prolonged (almost equal to adults) but decreases with increasing postnatal age. In patients with renal failure, non-renal elimination may compensate.

5.3 Preclinical safety data

There is evidence from animal studies that high doses of ceftriaxone calcium salt led to formation of concrements 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None.

6.2 Incompatibilities

Ceftriaxone solutions should not be mixed with other antimicrobial agents.

6.3 Shelf-life

24 Months

6.4 Special precautions for storage

Store below 30˚C. Protect from light.

6.5 Nature and content of container

Ceftriaxone is supplied in 15ml flint glass Vial USP Type III, is stoppered using 20mm grey bromo butyl rubber stopper and then sealed with 20mm white flip off Aluminum Seal.

Sealed glass vial is labeled and packed in mono carton along with pack insert.

Vial pack with one FFS pack of 10 ml Sterile Water for Injection.

6.6 Special precautions for disposal and other handling

The constituted solution should preferably be used immediately after preparation.

Directions for use:
Dissolve the contents of the vial with given sterile water for injection in 9.6 ml for I.V. use or 3.6ml for I.M. use.

Reconstituted I.M. solution is stable for 24 hours at 25°C and for 3 days if refrigerated (4°C).

Reconstituted I.V. solution is stable for 3 days at 25°C and for 10 days if refrigerated (4°C).

Frozen solutions should be thawed at room temperature before use and unused portions discared.

DO NOT RE-FREEZE.

7. MARKETING AUTHORISATION HOLDER

MARKET AUTHORIZATION HOLDER

Name: Zydus Healthcare Limited

Address: Ackruti Star, Unit No.: 103, MIDC, Andheri (E), Mumbai – 400 093, India

MANUFACTURER

Name : Zydus Healthcare Ltd.

Address : Survey No.: 49/3, 51/1, 51/2, Ringanwada village, Daman (U.T.) 396 210, India

8. MARKETING AUTHORISATION NUMBERS

CTD15287

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

April 2026

10. DATE OF REVISION OF THE TEXT

1/04/2026