IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 5, Issue 5, May 2025
Impact Factor: 7.67

Assessment and Case Analysis of Adverse Drug Reactions Associated with Ceftriaxone Administration in a Clinical Setting

Kiran H. Bibave[1], Ram R. Rathi[1], Mangesh P. Salunke[1], Dr. P. N. Sable[2]
SSP Shikshan Sanstha's Siddhi College of Pharmacy, Chikhali, Pune, Maharashtra, India[1,2]

Abstract: *Adverse drug reactions (ADRs) are unintended and harmful effects resulting from the use of medications, posing a significant challenge to patient safety worldwide. Ceftriaxone, a widely used third-generation cephalosporin antibiotic, is effective against a broad spectrum of infections but can also cause serious ADRs, including allergic reactions and hematologic complications. This observational case report was conducted at Manipal Hospital, Baner, Pune, to evaluate ADRs associated with the administration of injection ceftriaxone. The study focused on a 32-year-old female patient who developed an immediate allergic reaction following a single intravenous dose of ceftriaxone. Prompt treatment with antihistamines and corticosteroids resulted in recovery. The study emphasizes the importance of close monitoring, cautious prescribing, and comprehensive reporting of ADRs to enhance pharmacovigilance. While ceftriaxone remains a cornerstone in antimicrobial therapy, its misuse may contribute to antimicrobial resistance, highlighting the need for stewardship in clinical practice*

Keywords: Ceftriaxone, Adverse Drug Reactions (ADRs), Antibiotic Safet, Pharmacovigilance, Allergic Reaction, Case Report, Antimicrobial Resistance, Naranjo Algorithm, Cephalosporin, Drug Hypersensitivity

I. INTRODUCTION

Adverse drug reactions (ADRs), as defined by WHO, are harmful and unintended responses following drug administration for prevention, diagnosis, or treatment.[1] These reactions are unexpected and dangerous, emphasizing the importance of monitoring drug effects. Proper evaluation and reporting help reduce their impact and improve safety.[2] In Europe, ADRs cause significant illness and about 197,000 deaths yearly, accounting for 5% of hospital admissions and affecting a similar percentage of inpatients. Despite 2012 pharmacovigilance reforms, outdated data has led to a review of post-2000 studies on ADR prevalence.[3] ADRs significantly affect health and survival, especially in hospitalized patients, and are among the top ten causes of death in many countries. A study in Malaysia showed anti-infectives, especially antibiotics, caused most ADRs in children under two. The NPRA and MADRAC oversee drug safety in Malaysia, but more data is needed on antibiotic-related ADRs. This study at Hospital Pulau Pinang investigates ADRs linked to antibiotics to support prevention and safety.[4] ADRs can weaken trust in doctors, prompting self-medication and added risks. They cause 5% of admissions and affect 10%–20% of inpatients, sometimes going undetected or being fatal in 0.1%–0.3% of cases.Managing ADRs quickly is vital, though diagnosis can be costly.[5]The ADR definition now includes misuse, errors, abuse, and off-label use, affecting reporting but not treatment. Studies from the USA and UK confirm ADRs still cause hospital issues in 5%–10% of patients. Even if not severe, they bring risks, costs, and strain doctor-patient relations. Drugs often linked to ADRs include antiplatelets, anticoagulants, cytotoxics, immunosuppressants, diuretics, antidiabetics, and antibiotics; fatalities often involve antithrombotics with NSAIDs.[6] Ceftriaxone, a third-generation cephalosporin, is widely used for its strong, broad antibacterial effect and low toxicity. It treats infections in the urinary tract, respiratory tract, skin, bones, joints, blood, ears, and genital areas, as well as meningitis, Lyme disease, and post-surgical infections.[7] However, its overuse—due to prolonged treatment, incorrect doses, and long hospital stays—has worsened antimicrobial resistance. This leads to poorer outcomes and higher healthcare costs, with studies showing significant added expenses from ceftriaxone misuse.[8]

IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 5, Issue 5, May 2025
Impact Factor: 7.67

Evaluation of ADR

The earliest known case of an adverse drug reaction (ADR) was reported on January 29, 1848, when Hannah Greener died after being given chloroform anesthesia for surgery on an ingrown toenail. Her death was linked to ventricular fibrillation caused by the chloroform. Although the case was reported in *The Lancet*, there was no established ADR monitoring system until after the Thalidomide crisis. The 20th century saw the introduction of more powerful medications, which led to a rise in the number and severity of ADRs. One major case before the Thalidomide incident was the 1937 Sulphanilamide disaster, which caused over 100 deaths due to the toxic solvent diethylene glycol used in the formulation. [9,10]

II. CLASSIFICATION OF ADVESE DRUG REACTION

Based on Mechanism (Rawlins & Thompson Classification)[11,12,13,14,15,16]

- **Type A (Augmented) Reaction:** Predictable, dose-dependent (e.g., bleeding with anticoagulants).
- **Type B (Bizarre) Reaction:** Unpredictable, immune-mediated/genetic (e.g., anaphylaxis with penicillin).
- **Type C (Chronic) Reaction:** Due to long-term use (e.g., osteoporosis with corticosteroids).
- **Type D (Delayed) Reaction:** Appears long after exposure (e.g., cancer with chemotherapy).
- **Type E (End of Use) Reaction:** Withdrawal effects (e.g., opioid withdrawal).
- **Type F (Failure) Reaction:** Drug inefficacy (e.g., antibiotic resistance).

Based on Severity[13]

- **Mild:** Nausea, dizziness, headache.
- **Moderate:** Rash, diarrhoea, increased liver enzymes.
- **Severe:** Anaphylaxis, organ failure, life-threatening conditions.

Reporting Of ADR:

Reporting adverse drug reactions (ADRs) plays a vital role in pharmacovigilance, helping to ensure patient safety and strengthen drug regulations globally. Accurate ADR reporting supports the identification, evaluation, understanding, and prevention of adverse effects or other medicine-related issues, thereby improving healthcare quality.[13] For more than five decades, spontaneous reporting systems such as the UK's Yellow Card Scheme have been crucial in identifying ADRs by gathering data on suspected reactions to drugs and vaccines. [17,18] Although around 25,000 reports are submitted each year, underreporting is a significant problem, with fewer than 5% of ADRs being documented.In 2014, NHS England and the MHRA took steps to address this by including medication error-related ADRs in the Yellow Card Scheme.[6]

III. HISTORY OF CEFTRIAXONE ADR

In pediatric patients, ceftriaxone may cause renal side effects such as urolithiasis in those under 18, which can potentially lead to acute kidney injury.[19] Due to its ability to bind with calcium, ceftriaxone may form deposits that cause gallbladder complications like biliary sludge or stones, though these effects are uncommon in children. It can also trigger immune-mediated hemolysis, breaking down red blood cells.In neonates, ceftriaxone may increase bilirubin levels by displacing it from blood proteins, raising the risk of jaundice, especially in infants already showing elevated bilirubin.[29] One patient developed severe thrombocytopenia after five days of ceftriaxone, with platelet levels dropping from 65×10^9/L to 3×10^9/L, accompanied by bleeding—indicating drug-induced thrombocytopenia.[20] In another case, a 4-year-old girl being treated for acute laryngotracheal bronchitis developed drug-induced immune hemolyticanemia (DIIHA), experiencing hypotension, weakness, hemolysis, and a hemoglobin drop from 133 g/L to 48 g/L. Ceftriaxone was stopped, and after treatment with steroids and supportive care, she recovered and was discharged after 13 days with normal lab results.[21] A 50-year-old HIV-positive woman on antiretroviral and anti-tubercular medication developed a maculopapular rash, itching, facial swelling, and lip swelling within three days of ceftriaxone therapy. The drug was discontinued, and the hypersensitivity reaction was suspected to be caused by ceftriaxone.[22] A 59-year-old hypertensive

IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 5, Issue 5, May 2025
Impact Factor: 7.67

female with nephrotic-range proteinuria experienced a severe anaphylactic reaction—itching, shortness of breath, stridor, hypotension, and hypoxia—within five minutes of IV ceftriaxone despite a negative sensitivity test. She was treated immediately with adrenaline, antihistamines, steroids, and supportive care, recovered, and was later discharged with oral antibiotics.[23]

IV. AIM & OBJECTIVE

AIM

This descriptive case report study aims to evaluate adverse drug reactions (ADRs) associated with the administration of INJ. Ceftriaxone.

OBJECTIVES

- To determine the incidence of adverse drug reactions (ADRs) following the administration of injection ceftriaxone.
- To characterize the types and clinical manifestations of ceftriaxone-related ADRs.
- To examine the relationship between patient-specific factors (e.g., age, gender, underlying conditions) and the occurrence of ADRs.
- To perform a causality assessment using Naranjo's Algorithm to establish the likelihood that ceftriaxone was responsible for the observed ADRs.
- To contribute to pharmacovigilance efforts by documenting and analyzing real-world cases of ceftriaxone-induced ADRs.

V. MATERIALS AND METHODS

Study Title: Assessment of Adverse Drug Reactions Associated with INJ. Ceftriaxone

Study Location & Duration:

Location: Manipal Hospital, Baner, Pune

Duration:6/02/2024 TO 17/02/2024

Study Design:

Observational case report study

Source of Study:

Study Population: OPD patients visiting Manipal Hospital, Baner.

Inclusion Criteria:

- Patients with complete demographic details (name, age, gender)
- Patients prescribed INJ. Ceftriaxone

Exclusion Criteria:

Patients with incomplete medical records

Case Study Parameters:

Patient Observations:

Dosage and dosage form

Route of administration

Data Collection:

Adverse drug reactions (ADRs) will be analyzed based on:

✓ Patient demographics

✓ Disease conditions

✓ Nature and type of ADRs

✓ Drug characteristics

✓ Clinical outcomes

IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 5, Issue 5, May 2025
Impact Factor: 7.67

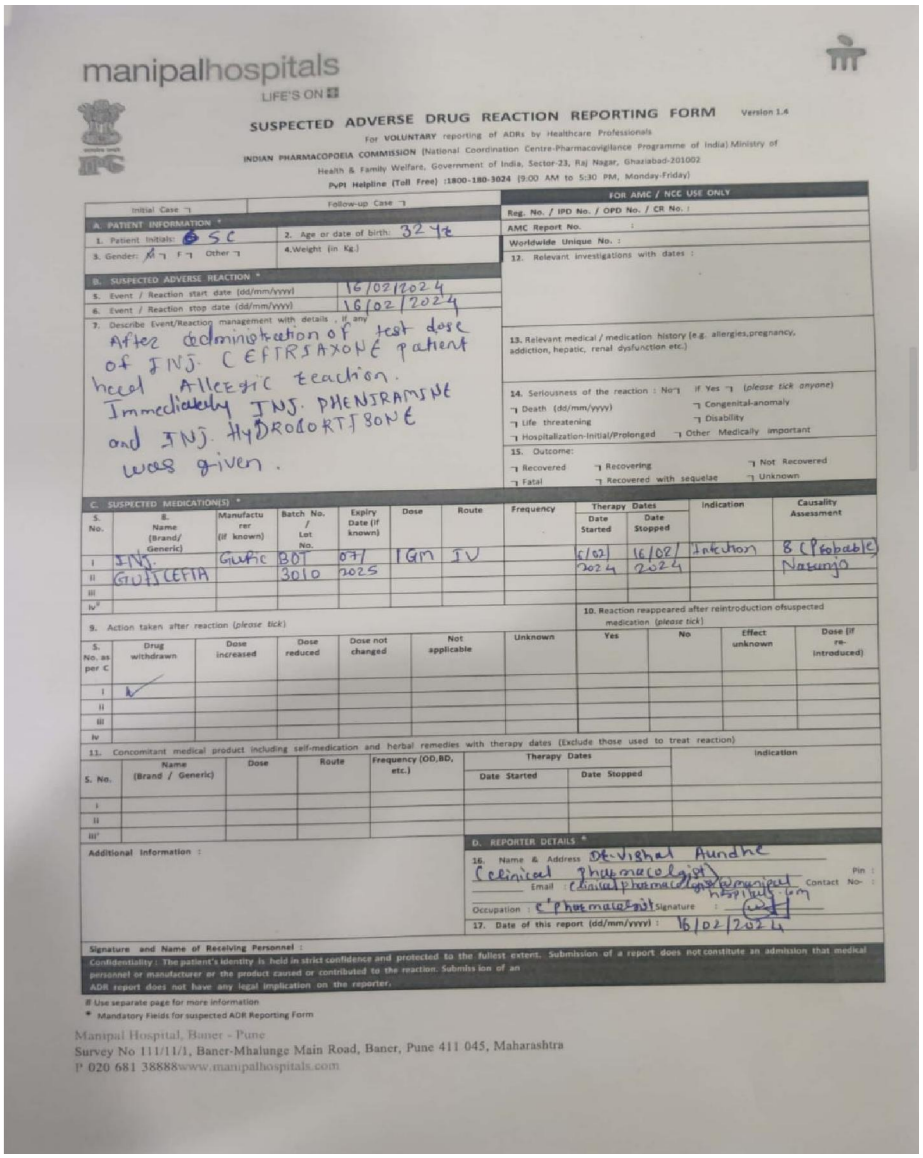
Criteria for Identifying ADRs:

Physician-confirmed ADRs will be recorded and included in the study.

ADR Analysis:

Classification and description of reported ADRs

Causality assessment using **Naranjo's Algorithm** to determine the likelihood of drug-related adverse reactions.



manipalhospitals
LIFE'S ON

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM Version 1.4

For VOLUNTARY reporting of ADRs by Healthcare Professionals
INDIAN PHARMACOPOEIA COMMISSION (National Coordination Centre-Pharmacovigilance Programme of India) Ministry of Health & Family Welfare, Government of India, Sector-23, Raj Nagar, Ghaziabad-201002
PvPI Helpline (Toll Free) :1800-180-3024 (9:00 AM to 5:30 PM, Monday-Friday)

Initial Case ☐ Follow-up Case ☐

FOR AMC / NCE USE ONLY
Reg. No. / IPD No. / OPD No. / CR No. :
AMC Report No. :
Worldwide Unique No. :

A. PATIENT INFORMATION *
1. Patient Initials: SC
2. Age or date of birth: 32 Yr
3. Gender: ☒ M ☐ F ☐ Other
4. Weight (in Kg.)

B. SUSPECTED ADVERSE REACTION *
5. Event / Reaction start date (dd/mm/yyyy): 16/02/2024
6. Event / Reaction stop date (dd/mm/yyyy): 16/02/2024
7. Describe Event/Reaction management with details , if any: After administration of test dose of INJ. CEFTRIAXONE patient heeal Allergic reaction. Immediately INJ. PHENIRAMINE and INJ. HYDROCORTISONE was given.

12. Relevant investigations with dates :
13. Relevant medical / medication history (e.g. allergies,pregnancy, addiction, hepatic, renal dysfunction etc.)
14. Seriousness of the reaction : No ☐ If Yes ☐ (please tick anyone)
☐ Death (dd/mm/yyyy) ☐ Congenital-anomaly
☐ Life threatening ☐ Disability
☐ Hospitalization-Initial/Prolonged ☐ Other Medically important
15. Outcome:
☐ Recovered ☐ Recovering ☐ Not Recovered
☐ Fatal ☐ Recovered with sequelae ☐ Unknown

C. SUSPECTED MEDICATION(S) *

S. No.	8. Name (Brand/ Generic)	Manufacturer (If known)	Batch No. / Lot No.	Expiry Date (If known)	Dose	Route	Frequency	Therapy Dates: Date Started	Therapy Dates: Date Stopped	Indication	Causality Assessment
I	INJ. GUFTICEFTA	Glufic	BOT 3010	07/2025	1GM	IV		16/02/2024	16/02/2024	Infection	B (Probable) Naranjo
II											
III											
IV											

9. Action taken after reaction (please tick)

S. No. as per C	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown
I	✓					
II						
III						
IV						

10. Reaction reappeared after reintroduction of suspected medication (please tick)

Yes	No	Effect unknown	Dose (If re-introduced)

11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)

S. No.	Name (Brand / Generic)	Dose	Route	Frequency (OD,BD, etc.)	Therapy Dates: Date Started	Therapy Dates: Date Stopped	Indication
I							
II							
III							

Additional Information :

D. REPORTER DETAILS *
16. Name & Address: Dr. Vishal Aundhe Clinical Pharmacologist Manipal Hospital Baner
Email : Clinical Pharmacologist@manipalhospitals.com Contact No- :
Occupation : Clinical Pharmacologist Signature :
17. Date of this report (dd/mm/yyyy) : 16/02/2024

Signature and Name of Receiving Personnel :

Confidentiality : The patient's identity is held in strict confidence and protected to the fullest extent. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction. Submission of an ADR report does not have any legal implication on the reporter.

Use separate page for more information
* Mandatory Fields for suspected ADR Reporting Form

Manipal Hospital, Baner - Pune
Survey No 111/11/1, Baner-Mhalunge Main Road, Baner, Pune 411 045, Maharashtra
P 020 681 38888www.manipalhospitals.com

VI. CASE STUDY

PATIENT INFORMATION

Patient Initials: SC

- **Age:** 32 yrs
- **Sex:** Female
- **Hospital/Clinic:** Manipal Hospital, Baner, Pune

IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 5, Issue 5, May 2025
Impact Factor: 7.67

SUSPECTED ADVERSE DRUG REACTION DETAILS

- **Drug:** INJ. GUFICEFTA 1g
- **Batch No.:** BOT3010
- **Dose:** 1g
- **Route:** Intravenous (IV)
- **Expiry Date:** 07/2025
- **Frequency:** Once
- **Therapy Dates:**
- **Date Started:** 16/02/2024
- **Date Stopped:** 16/02/2024
- **Indication:** Allergic Reaction

ADVERSE DRUG REACTION

After administration of ceftriaxone, the patient developed an immediate allergic reaction.

Treatment Administered:

- INJ. Pheniramine
- INJ. Hydricortisone

REPORTER DETAILS

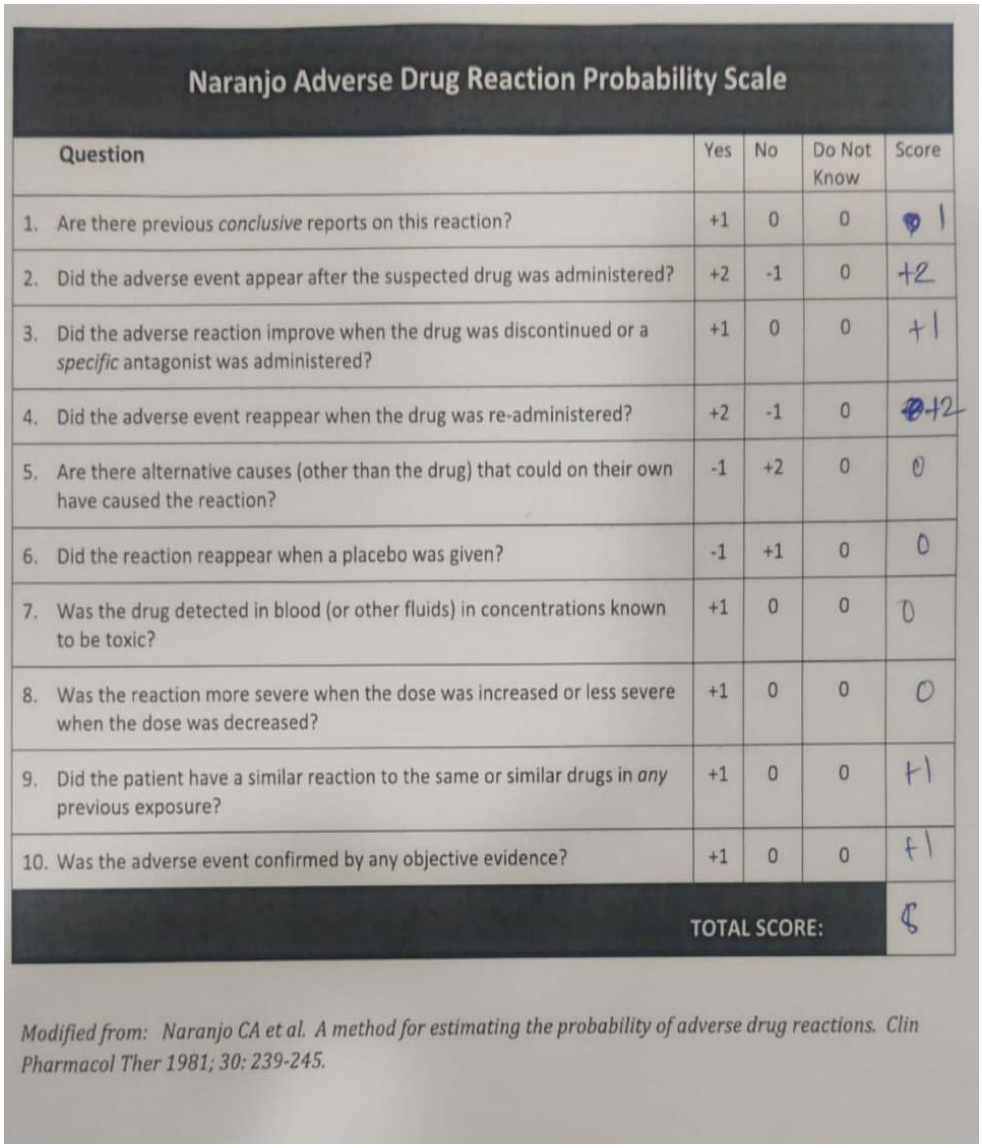
- **Name:** Dr. Vishal Aundhe
- **Address:** Clinical Pharmacologist, Manipal Hospitals.
- **Contact:** 9689721151
- **Occupation:** Clinical Pharmacologist
- **Date of Report:** 16/02/2024

SUSPECTED DRUG AND ITS PHARMACOLOGY

- **Class of Drug:** Third-Generation Cephalosporin Antibiotics.
- **Brand Name:** INJ. GUFICEFTA
- **Dose and Strength:** Injection - 1g

DOI: 10.48175/IJARSCT-26672

IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 5, Issue 5, May 2025
Impact Factor: 7.67



Naranjo Adverse Drug Reaction Probability Scale

Question	Yes	No	Do Not Know	Score
1. Are there previous *conclusive* reports on this reaction?	+1	0	0	+1
2. Did the adverse event appear after the suspected drug was administered?	+2	-1	0	+2
3. Did the adverse reaction improve when the drug was discontinued or a *specific* antagonist was administered?	+1	0	0	+1
4. Did the adverse event reappear when the drug was re-administered?	+2	-1	0	+2
5. Are there alternative causes (other than the drug) that could on their own have caused the reaction?	-1	+2	0	0
6. Did the reaction reappear when a placebo was given?	-1	+1	0	0
7. Was the drug detected in blood (or other fluids) in concentrations known to be toxic?	+1	0	0	0
8. Was the reaction more severe when the dose was increased or less severe when the dose was decreased?	+1	0	0	0
9. Did the patient have a similar reaction to the same or similar drugs in *any* previous exposure?	+1	0	0	+1
10. Was the adverse event confirmed by any objective evidence?	+1	0	0	+1
			TOTAL SCORE:	6

Modified from: Naranjo CA et al. A method for estimating the probability of adverse drug reactions. Clin Pharmacol Ther 1981; 30: 239-245.

CEFTRIAXONE:

Ceftriaxone is a third-generation cephalosporin with a long half-life, which allows it to be administered once daily. It is effective against a wide variety of bacteria and is commonly prescribed for conditions like meningitis, Salmonella infections, and gonorrhea.The drug is eliminated through both the bile and urine, so dosage adjustments are typically unnecessary unless there is significant impairment of both kidney and liver function.[24] Ceftriaxone can displace bilirubin from albumin, which can be risky for newborns with high bilirubin levels. Rare side effects include skin reactions, biliary sludge, kidney stones, and severe hemolysis.[25]

DOSAGE AND ADMINISTRATION[25,26]

Ceftriaxone can be administered intravenously (IV) or intramuscularly (IM), but it should not be mixed with calcium-containing solutions due to the risk of precipitation. If both are required, they must be given separately, with proper flushing of the IV line.

IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 5, Issue 5, May 2025
Impact Factor: 7.67

Neonates: Ceftriaxone is not recommended for newborns with elevated bilirubin levels or those who need calcium-containing IV solutions, as this could lead to life-threatening complications.

Pediatrics: For skin and soft tissue infections, the recommended dose is 50–75 mg/kg per day, up to a maximum of 2 grams. A single 50 mg/kg IM dose (up to 1 gram) is given for ear infections. Serious infections require 50–75 mg/kg daily, divided every 12 hours, while meningitis treatment begins with 100 mg/kg (up to 4 grams), followed by the same daily dose for 7–14 days.

Adults: The typical dose is 1–2 grams per day, with 2–4 grams required for MSSA infections. Uncomplicated gonorrhea is treated with a 250 mg IM dose. For surgical prophylaxis, 1 gram IV is administered 30 minutes to 2 hours before surgery. The treatment duration ranges from 4–14 days, or at least 10 days for Streptococcus pyogenes infections. No dose adjustments are required for patients with kidney or liver impairment.

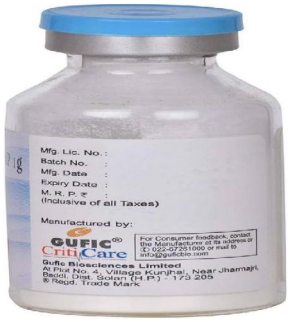
Brand:INJ. GUFICEFTA

Manufacturer: Gufic Bioscience Pvt Ltd

Composition:

Ceftriaxone

(Usually available as 1.5 g IV)



MECHANISM OF ACTION OF CEFTRIAXONE:

Ceftriaxone is a bactericidal antibiotic that kills bacteria by preventing the formation of their cell walls. It binds to penicillin-binding proteins (PBPs), which are essential for linking peptidoglycan chains in the bacterial cell wall. This interference compromises the cell wall structure, causing the bacteria to rupture and die. Ceftriaxone also remains effective against some β-lactamase enzymes, including penicillinases and cephalosporinases, allowing it to work against a wide range of Gram-positive and Gram-negative bacteria.[25]

PHARMACOKINETIC PROFILE OF CEFTRIAXONE: [27]

1. Absorption

Ceftriaxone is administered via intravenous (IV) or intramuscular (IM) routes, with peak plasma concentrations (*Cmax*) varying based on dosage and method of administration.

IV Administration:

0.5g → *Cmax* ≈ 82 mg/L

1g → *Cmax* ≈ 151 mg/L

2g → *Cmax* ≈ 257 mg/L

After 24 hours of a 2g IV dose, plasma levels range from 12–20 mg/L.

IM Administration:

0.5g → *Cmax* ≈ 38 mg/L (reached in 2–3 hours)

1g → *Cmax* ≈ 76 mg/L (reached in 2–3 hours)

Repeated daily IV administration of 2g leads to an 8% increase in *Cmax*, while repeated IM administration of 1g results in an 11% accumulation.

IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 5, Issue 5, May 2025
Impact Factor: 7.67

2. Distribution

Ceftriaxone is extensively distributed in body fluids and tissues.
Volume of Distribution (Vd): Ranges from 5.8 to 15.5L in healthy individuals.
Protein Binding:
Reversibly binds to albumin.
Binding decreases with increasing plasma concentration (≈95% at >70 mg/L to ≈58% at 600 mg/L).
Biliary Concentration:
1 hour after a 1g IV dose → Biliary concentration ≈153 mg/L
3 hours after a 1g IV dose → Biliary concentration ≈44 mg/L

3. Metabolism and Elimination

Ceftriaxone is mainly excreted unchanged via renal and biliary pathways.
Renal Excretion: 45–60% of a 0.5 to 3g dose is eliminated in urine within 48 hours.
Biliary Excretion: The remainder is secreted into bile and excreted in feces as inactive compounds.
Plasma Clearance:
0.5g IV dose → 0.61 to 1.0 L/h
2g IV dose → 1.18 to 1.29 L/h

4. Half-Life (t½)

The elimination half-life in healthy adults is approximately 6 to 9 hours, significantly longer than other cephalosporins (0.6–4.4 hours).
The half-life remains consistent, irrespective of dose, frequency, or route of administration.

Indications:

Ceftriaxone is a broad-spectrum cephalosporin antibiotic commonly prescribed for a wide range of bacterial infections. It is highly effective in treating meningitis, except when caused by *Listeria monocytogenes*, due to its excellent penetration into cerebrospinal fluid. It is widely used for both community-acquired and hospital-acquired pneumonia. Ceftriaxone also plays a key role in managing urinary tract infections (UTIs) caused by sensitive organisms and is a first-line therapy for gonorrhea caused by *Neisseria gonorrhoeae*. It is particularly valuable in treating typhoid fever (*Salmonella typhi*), especially in regions with increasing antibiotic resistance. Other important uses include treating skin and soft tissue infections, bone and joint infections, and infections of the biliary tract, making ceftriaxone versatile in clinical practice.[28]

Contraindications:

Ceftriaxone should not be used in neonates, especially premature infants, as it may displace bilirubin from albumin, increasing free bilirubin levels and raising the risk of kernicterus. This risk is more pronounced in infants under one month of age or those under one year with existing risk factors. It is also contraindicated in individuals allergic to cephalosporin antibiotics. In neonates younger than 28 days, ceftriaxone must not be co-administered with calcium-containing intravenous solutions due to the risk of fatal calcium precipitation in the lungs and kidneys. Therefore, it should be avoided in neonates expected to receive calcium-containing infusions, given the potential for calcium-chelate formation.[29]

Drug Interactions with Ceftriaxone:[29,30,31,32]

Ceftriaxone interacts adversely with calcium-containing IV solutions, especially in neonates, where it may form fatal precipitates in vital organs. Thus, simultaneous administration must be avoided. When used with warfarin, ceftriaxone may increase anticoagulant effects, heightening bleeding risk and requiring close INR monitoring. Combining ceftriaxone with aminoglycosides (e.g., gentamicin) can amplify kidney toxicity, though they may exhibit synergistic antimicrobial effects; hence, renal function should be closely observed. Although data are limited, ceftriaxone may

IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 5, Issue 5, May 2025
Impact Factor: 7.67

lower the effectiveness of oral contraceptives, so supplementary contraceptive methods are recommended during treatment.

USES [24,33,34]

- **Community-Acquired Infections**: Treats conditions like meningitis, pneumonia, acute otitis media, gonorrhea, and pyelonephritis.
- **Nosocomial Infections**: Effective for severe hospital-acquired infections, including Gram-negative bacteremia, pneumonia, and spontaneous bacterial peritonitis .
- **Surgical Prophylaxis**: Used to prevent infections in high-risk surgeries, including colorectal and orthopedic procedures.
- **Neuroprotectiveand Analgesic:** Shows promise in reducing neuroinflammation and amyloid plaques, with potential pain-relieving properties.
- **Antimicrobial Resistance:** Increasing resistance in pathogens like gonorrhea and Salmonella due to overuse in humans and animals.
- **Additional Uses:** Also used for endocarditis, Lyme disease, and septicemia in serious infections.
- **Meningitis**: Effective in treating bacterial meningitis caused by Neisseria meningitidis, Streptococcus pneumoniae, and Haemophilus influenzae.
- **Pneumonia:** Used to treat both community-acquired and hospital-acquired pneumonia, especially when resistant organisms are suspected.
- **Acute Otitis Media:** Used in treating middle ear infections in children, particularly when other antibiotics fail.
- **Gonorrhea:** A primary treatment for uncomplicated gonococcal infections, particularly when resistance is present.
- **Pyelonephritis:** Treats acute kidney infections, especially in hospitalized patients with complicated infections.
- **Urinary Tract Infections (UTIs):** Used for both uncomplicated and complicated UTIs, including those caused by resistant strains.
- **Endocarditis:** In combination with other antibiotics, ceftriaxone is used to treat bacterial endocarditis.
- **Septicemia**: Treats bloodstream infections, including sepsis caused by susceptible organisms.
- **Spontaneous Bacterial Peritonitis (SBP):** Used for treating infections in patients with cirrhosis and ascites.
- **Bone and Joint Infections:** Treats osteomyelitis and septic arthritis caused by susceptible pathogens.

VII. RESULT

In this case, a 32-year-old female patient received a single intravenous dose of 1g ceftriaxone (brand name GUFICEFTA). Shortly after administration, the patient developed an immediate allergic reaction characterized by symptoms consistent with anaphylaxis. The reaction was promptly managed with intravenous injections of pheniramine and hydrocortisone, resulting in effective resolution.

The Naranjo Adverse Drug Reaction (ADR) Probability Scale is a standardized tool used to determine the likelihood that an adverse drug reaction is directly related to a specific medication. It comprises ten questions, each scored -1, 0, or +1 based on the response. The cumulative score ranges from -4 to +13, with higher scores indicating a greater probability that the ADR is drug-induced. Scores from 5 to 8 correspond to a "Probable" ADR, while scores of 1 to 4 indicate a "Possible" ADR.

Applying the Naranjo scale to this case yields a score of 8, indicating a "Probable" causal relationship between ceftriaxone administration and the observed allergic reaction. The reaction occurred immediately after drug administration, which aligns with a recognized pattern of hypersensitivity reactions associated with ceftriaxone. This is consistent with known adverse reactions of cephalosporin antibiotics.

DOI: 10.48175/IJARSCT-26672

IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 5, Issue 5, May 2025
Impact Factor: 7.67

VIII. DISCUSSION

A 32-year-old female patient presented to the hospital with symptoms of a bacterial infection. She was prescribed Injection Ceftriaxone 1g once daily via the intravenous route. Shortly after administration of the first dose, the patient developed an immediate allergic reaction, characterized by rash and itching. No other new medications were initiated at that time, and concomitant treatment included only supportive care. The patient's allergy history was not significant for beta-lactam antibiotics.

The Naranjo Adverse Drug Reaction Probability Scale scored a total of 8, indicating that the reaction was a probable adverse drug reaction. The reaction was classified as an immediate-type allergic response. Ceftriaxone was discontinued and the patient was treated with intravenous injections of pheniramine and hydrocortisone to manage the allergic symptoms. The patient's condition improved, and no rechallenge was attempted.

The study further noted that ceftriaxone is widely used due to its broad-spectrum activity. It works by inhibiting bacterial cell wall synthesis and effectively treats infections such as pneumonia, meningitis, urinary tract infections, gonorrhea, and skin infections. Its long half-life allows for convenient once-daily dosing, and its dual elimination via renal and biliary routes permits dosing without adjustment in most patients. However, ceftriaxone is associated with rare complications, including biliary sludge and kidney stones, due to its excretion pathways. Additionally, inappropriate use of ceftriaxone has contributed to rising antimicrobial resistance in pathogens such as *Salmonella* spp. and *Neisseria gonorrhoeae*.

This case highlights the importance of early identification of adverse drug reactions and the critical role of reporting to strengthen pharmacovigilance. Judicious use of antibiotics is essential to reduce the risk of resistance and preserve the clinical efficacy of these important drugs.

IX. CONCLUSION

In the present study, the patient was prescribed ceftriaxone, and after a single dose, developed an immediate allergic reaction characterized as a serious adverse drug reaction (ADR). This study is an observational report of an immediate ADR following drug administration. Appropriate treatment was promptly initiated to manage the reaction. The Naranjo scale score of 8 indicates a probable ADR, suggesting a temporal relationship between the administration of ceftriaxone and the observed reaction. The reaction followed a recognized pattern consistent with the suspected drug and can be explained by the patient's characteristics and the drug's known profile.

It is concluded that there is a causality association between the adverse drug reaction and the suspected medication. Therefore, careful patient monitoring, judicious prescribing, and enhanced pharmacovigilance are recommended to ensure patient safety and minimize the risks associated with ceftriaxone use. Further investigation is warranted to confirm and better understand these adverse drug reactions.

REFERENCES

[1]. WHO. A guide to detecting and reporting adverse drug reactions. WHO, Geneva, 2002.

[2]. Jiang, H., Lin, Y., Ren, W., Fang, Z., Liu, Y., Tan, X., ... & Zhang, N. (2022). Adverse drug reactions and correlations with drug–drug interactions: A retrospective study of reports from 2011 to 2020. *Frontiers in pharmacology*, *13*, 923939.

[3]. Bouvy, J. C., De Bruin, M. L., &Koopmanschap, M. A. (2015). Epidemiology of adverse drug reactions in Europe: a review of recent observational studies. *Drug safety*, *38*, 437-453.

[4]. Arulappen, A. L., Danial, M., & Sulaiman, S. A. (2018). Evaluation of reported adverse drug reactions in antibiotic usage: A retrospective study from a tertiary care hospital, Malaysia. *Frontiers in pharmacology*, *9*, 809.

[5]. By Stephanie N. Schatz, Pharm.D., BCPS; and Robert J. Weber, Pharm.D., BCPS

[6]. Reviewed by Kyle E. Hultgren, Pharm.D.; Erin M. Timpe Behnen, Pharm.D., BCPS; and Michael C. Barros, Pharm.D., BCPS, BCACP.

[7]. Coleman, J. J., & Pontefract, S. K. (2016). Adverse drug reactions. *Clinical Medicine*, *16*(5), 481-485.

IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 5, Issue 5, May 2025
Impact Factor: 7.67

[8]. Sileshi, A., Tenna, A., Feyissa, M., &Shibeshi, W. (2016). Evaluation of ceftriaxone utilization in medical and emergency wards of Tikur Anbessa specialized hospital: a prospective cross-sectional study. *BMC Pharmacology and Toxicology*, *17*, 1-10.Patel, T.K.; Patel, P.B. Incidence of adverse drug reactions in Indian hospitals: A systematic review of prospective studies. Curr. Drug Saf. 2016, 11, 128–136

[9]. Lee H, Jung D, Yeom JS, Son JS, Jung S, Kim YS. Evaluation of ceftriaxoneutilization at multi-center study. Korean J Intern Med. 2009;24(4):374–80

[10]. Avorn, J. (2012). Two centuries of assessing drug risks. *New England Journal of Medicine*, *367*(3), 193-197.

[11]. Rohilla, A., & Yadav, S. (2013). Adverse drug reactions: an overview. *Int J Pharmacol Res*, *3*(1), 10-2.

[12]. Park, B. K., Pirmohamed, M., &Kitteringham, N. R. (1992). Idiosyncratic drug reactions: a mechanistic evaluation of risk factors. *British journal of clinical pharmacology*, *34*(5), 377.

[13]. Angeline, A., &Perumaloo, P. (2015). From evolution to prevention of adverse drug reaction. *Int J Pharm Pract*, *5*, 1170-1177.

[14]. Bereda, G. (2021). Delineation and Classifications of Adverse Drug Reaction: Brief Communication. *Chemistry*, *7*(6), 122-124..

[15]. Choudhary, E., Jain, S., Mahto, S., & Ahuja, D. (2023). Adverse drug reactions: Identification, prevention, and management. *International Journal for Multidisciplinary Research*, 5(6), 25–32.

[16]. Stephens, M. D. B. (1998). Definitions and classifications of adverse reaction terms. *The detection of new adverse reactions, 4th edn. London: Macmillan Reference*, 32-44.

[17]. Yadav, S. (2008). Status of adverse drug reaction monitoring and pharmacovigilance in selected countries. *Indian journal of pharmacology*, *40*(Suppl 1), S4-S9.

[18]. South African Health Products Regulatory Authority. (2020). *Adverse drug reaction (ADR) reporting guideline for healthcare professionals* . https://www.sahpra.org.za/wp-content/uploads/2020/04/ADR-Reporting-Guideline_HCPs_v1_for-commenting_March-2020.pdf

[19]. Pacifici, G. M., & Marchini, G. (2017). Clinical pharmacology of ceftriaxone in neonates and infants: effects and pharmacokinetics. *International Journal of Pediatrics*, *5*(9), 5751-5778.

[20]. Jacquot, C., Moayeri, M., Kim, B., Shugarts, S., Lynch, K. L., & Leavitt, A. D. (2013). Prolonged ceftriaxone-induced immune thrombocytopenia due to impaired drug clearance: a case report. *Transfusion*, *53*(11), 2715-2721.

[21]. Liu, W., & Yu, D. (2014). Adverse drug reactions during ceftriaxone treatment can cause severe hemolysis. *Pediatric Allergy & Immunology*, *25*(1).

[22]. Krishna, dr.allu&vamaraju, upajna&pavan, k.mahesh&deepika, b.navya. (2020). A case report on ceftriaxone induced maculopapular rash. World journal of current medical and pharmaceutical research. 02. 92-93. 10.37022/wjcmpr.2020.2201.

[23]. Devada, Sindhu & Saini, Bhawna & Saini, Sandeep & Kumar, Dhoot. (2022). Ceftriaxone Induced Anaphylaxis Reaction Following Negative Intradermal Skin Tested Patient: A Rare Case Report. International Journal of Pharmaceutical Sciences Review and Research. 66-69. 10.47583/ijpsrr.2022.v75i01.011.

[24]. Rodríguez, A. T., i Barceló, A. F., González, M. B., Esnal, D. E., Muner, D. S., Martínez, J. A., & Creus, M. T. (2024). Clinically important pharmacokinetic drug-drug interactions with antibacterial agents. *Revista Española de Quimioterapia*, *37*(4), 299.

[25]. Khan, M. Y., Roy, M., Rawal, R. K., & Bansal, U. K. (2017). A review-ceftriaxone for life. *Asian Journal of Pharmaceutical Research*, *7*(1), 35-48.

[26]. Kadam, S. S., Udamale, N. S., &Khopde, A. G. (2023). Ceftriaxone serious infection disease in septicemia. *International Journal of Novel Research and Development*, 8(10).

[27]. Lamb, H. M., Ormrod, D., Scott, L. J., &Figgitt, D. P. (2002). Ceftriaxone: an update of its use in the management of community-acquired and nosocomial infections. *Drugs*, *62*(7), 1041-1089.

IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 5, Issue 5, May 2025
Impact Factor: 7.67

[28]. Malik, M., Alagab, M., Maatoug, M., Zahran, F., Elmubarak, A., Alhaddad, T., & Omer, S. (2020). Evaluation of the appropriate use of ceftriaxone in internal medicine wards of Wad Medani Teaching Hospital in Sudan. *Int. J. Med. Sci. Clin. Invent*, *7*, 4757-4765.

[29]. Bereda, G. (2022). Ceftriaxone in pediatrics: Indication, adverse drug reaction, contraindication and drug interaction. *Journal of Addiction Therapy and Research*, *6*(1), 007-009.

[30]. Biner B, Oner N, Celtik C, Bostancioğlu M, Tunçbilek N, et al. Ceftriaxone-associated biliary pseudolithiasis in children. J Clin Ultrasound. 2006; 34: 217-222.

[31]. Steadman, Emily & Raisch, Dennis & Bennett, Charles & Esterly, John & Becker, Tischa &Postelnick, Michael & McKoy, June & Trifilio, Steve & Yarnold, Paul & Scheetz, Marc. (2010). Evaluation of a Potential Clinical Interaction between Ceftriaxone and Calcium. Antimicrobial agents and chemotherapy. 54. 1534-40. 10.1128/AAC.01111-09.

[32]. Saum, L. M., & Balmat, R. P. (2016). Ceftriaxone potentiates warfarin activity greater than other antibiotics in the treatment of urinary tract infections. *Journal of pharmacy practice*, *29*(2), 121-124.

[33]. Yimer EM, Hishe HZ, Tuem KB. Repurposing of the β-Lactam Antibiotic, Ceftriaxone for Neurological Disorders: A Review. Front Neurosci. 2019 Mar 26;13:236. doi: 10.3389/fnins.2019.00236. PMID: 30971875; PMCID: PMC6444273.

[34]. Shwetha Somakumar (2024). Clinical Efficacy and Safety of Ceftriaxone in Surgical Prophylaxis: A Systematic Review and Meta-Analysis. *Ind. J. Pharm. Edu. Res*, *58*(2s), s332-s339.

[35]. Meresa Bishaw, B., Tegegne, G. T., &Berha, A. B. (2021). Appropriate use of ceftriaxone in sub-Saharan Africa: a systematic review. Infection and Drug Resistance, 3477-3484.