NEW ZEALAND DATA SHEET

1 PRODUCT NAME

Cefazolin-AFT powder for injection equivalent to Cefazolin 500 milligram, 1 gram and 2 gram.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One vial of cefazolin sodium 524 mg equivalent to 500 mg cefazolin

One vial of cefazolin sodium 1048 mg equivalent to 1000 mg cefazolin

One vial of cefazolin sodium 2097 mg equivalent to 2000 mg cefazolin

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

White to off-white powder which reconstitutes with Sterile Water for Injection to give a colourless solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Cefazolin-AFT is indicated in the treatment of the following serious infections due to susceptible organisms:

Respiratory Tract Infection:

Due to *S. pneumoniae*, *Klebsiella sp*, *H. influenzae*, *Staph aureus* (including penicillinase-producing strains), and Group A β-haemolytic streptococci.

Injectable penicillin G benzathine is considered to be the medicine of choice in the treatment and prevention of streptococcal infections, including the prophylaxis of rheumatic fever.

Cefazolin-AFT is effective in the eradication of streptococci from the nasopharynx; however, data establishing the efficacy of cefazolin in the subsequent prevention of rheumatic fever are not available at present.

Genitourinary Tract Infections:

Due to *E. coli*, *P. mirabilis, Klebsiella sp*., and some strains of Enterobacter and enterococci.

Skin and Soft-tissue Infections:

Due to *Staph. aureus* (including penicillinase-producing strains) and Group A β- haemolytic streptococci and other strains of streptococci.

Biliary Tract Infections:

Due to E. coli, various strains of streptococci, *P. mirabilis, Klebsiella sp*., and *Staph. aureus*.

Bone and Joint Infections:

Due to *Staph. aureus*.

Septicaemia:

Due to *S. pneumoniae*, *Staph. aureus* (penicillin-susceptible and penicillin-resistant), *P. mirabilis, E. coli, and Klebsiella sp*.

Endocarditis:

Due to *Staph. aureus* (penicillin-susceptible and penicillin-resistant) and Group A β- haemolytic

streptococci.

Appropriate culture and susceptibility studies should be performed to determine susceptibility of the causative organism to Cefazolin-AFT.

Perioperative Prophylaxis:

The prophylactic administration of Cefazolin-AFT preoperatively, intraoperatively, and postoperatively may reduce the incidence of certain post-operative infections in patients undergoing surgical procedures that are classified as contaminated or potentially contaminated (e.g vaginal hysterectomy, or cholecystectomy in high-risk patients, such as those over 70 years of age who have acute cholecystitis, obstructive jaundice, or common bile-duct stones).

The perioperative use of Cefazolin-AFT may also be effective in surgical patients in whom infection at the operative site would present a serious risk (e.g. during open- heart surgery and prosthetic arthroplasty).

The prophylactic administration of Cefazolin-AFT should usually be discontinued within a 24 hour period after the surgical procedure. For surgery in which the occurrence of infection may be particularly devastating (e.g. open-heart surgery and prosthetic arthroplasty), the prophylactic administration of Cefazolin-AFT may be continued for 3 to 5 days following the completion of surgery. If there are signs of infection, specimens for cultures should be obtained for the identification of the causative organism so that appropriate therapy may be instituted.

4.2 Dose and method of administration

Cefazolin-AFT may be administered intramuscularly or intravenously after reconstitution. Total daily dosages are the same for either route of administration.

The intrathecal administration of Cefazolin-AFT is not an approved route of administration for this antibiotic. There have been reports of severe CNS toxicity including seizes when cefazolin has been administered in this manner.

Intramuscular Administration:

Reconstitute as directed in Table 1. Shake well until dissolved. The 500 mg vial can be reconstituted with 0.9% Sodium Chloride Injection, Sterile Water for Injection or Bacteriostatic Water for Injection. The 1 g and 2 g vial should only be reconstituted with Sterile Water for Injection or Bacteriostatic Water for Injection.

Cefazolin-AFT should be injected into a large muscle mass. Pain on injection is infrequent with Cefazolin-AFT.

Table 1 – Dilution Table

Vial Size	Diluent to be Added	Approx. Available Volume	Approx. Average Concentration
500mg	2 mL	2.2 mL	225 mg/mL
1g*	2.5 mL	3 mL	330 mg/mL
2g	5 mL	6mL	333 mg/mL

Intravenous Administration:

Cefazolin-AFT may be administered by intravenous injection or by continuous or intermittent infusion.

Intermittent Intravenous Infusion:

Cefazolin-AFT may be administered along with primary intravenous fluid management programmes in a volume control set or in a separate, secondary IV bottle. Reconstituted 500 mg, 1 g or 2g of Cefazolin-AFT may be diluted in 50 to 100 mL of one of the following intravenous solutions: 0.9% Sodium Chloride Injection, 5% or 10% Dextrose Injection, 5% Dextrose in Lactated Ringer's Injection, 5% Dextrose and 0.9% Sodium Chloride Injection (also may be used with 5% Dextrose and 0.45% or 0.2% Sodium Chloride Injection), Lactated Ringer's Injection, 5% or 10% Invert Sugar in Sterile Water for Injection, Ringer's Injection, Normosol-M in D5-W, Ionosol B with Dextrose 5% or Plasma-Lyte with 5% Dextrose.

Intravenous Injection:

Administer solution directly into vein or through tubing. Dilute the reconstituted 500 mg, 1 g or 2 g of Cefazolin- AFT in a minimum of 10 mL of Sterile Water for Injection. Inject solution slowly over a period of 3 to 5 minutes. Do not inject in less than 3 minutes.

Dosage:

The usual adult dosages are given in Table 2. In rare instances, doses up to 12g of cefazolin per day been used.

Table 2 – Usual Adult Dosage

Type of Infection	Dose	Frequency
Pneumococcal pneumonia	500 mg	12 hourly
Mild infections caused by susceptible gram positive cocci	250-500 mg	8 hourly
Acute uncomplicated urinary tract infections	1 g	12 hourly
Moderate to severe infections	500 mg-1 g	6-8 hourly
Severe, life threatening infections (e.g. endocarditis and septicaemia)*	1 g-1.5 g	6 hourly

Dosage adjustment for Patients with Reduced Renal Function:

Cefazolin-AFT may be used in patients with reduced renal function with the following dosage adjustments: Patients with a creatinine clearance ≥55 mL/min or a serum creatinine ≤1.5 mg% can be given full doses. Patients with creatinine clearance rates of 35 to 54 mL/min or serum creatinine of 1.6 to 3.0 mg % can also be given full doses but dosage should be restricted to at least 8-hour intervals. Patients with creatinine clearance rates of 11 to 34 mL/min or serum creatinine of 3.1 to 4.5 mg % should be given half the usual dose every 12 hours. Patients with creatinine clearance rates ≤10mL/min or serum creatinine ≥4.6mg % should be given half the usual dose every 18 to 24 hours. All reduced dosage recommendations apply after an initial loading dose appropriate to the severity of the infection. For information about peritoneal dialysis, see Pharmacokinetics.

Perioperative Prophylactic Use:

To prevent postoperative infection in contaminated or potentially contaminated surgery, the recommended doses are as follows:

- 1 g IV or IM administered 30 minutes to 1 hour prior to the start of surgery;
- For lengthy operative procedures (e.g. 2 hours or longer), 0.5 to 1 g I V or IM during surgery (administration modified according to the duration of the operative procedure); 0.5 to 1 g IV or IM every 6 to 8 hours for 24 hours postoperatively. It is important that:
    - The preoperative dose be given 30 minutes to 1 hour prior to the start of surgery so that adequate antibiotic levels are present in the serum and tissues at the time of the initial surgical incision and
    - If exposure to infections organisms is likely, Cefazolin-AFT be administered at appropriate intervals during surgery in order that sufficient levels of the antibiotic be present when needed.

- In surgery in which infection may be particularly devastating (e.g. open heart surgery and prosthetic arthroplasty), the prophylactic administration of Cefazolin-AFT may be continued for 3 to 5 days following the completion of surgery.

Children:

In children, a total daily dosage of 25 to 50 mg/kg of body weight, divided into 3 or 4 equal doses, is effective for most mild to moderately severe infections (Table 3). Total daily dosage may be increased to 100 mg/kg of body weight for severe infections.

Table 3 – Paediatric dosage guide

Weight	**25 mg/kg/day divided into 3 doses**		**25 mg/kg/day divided into 4 doses**	
Kg	**Approx. single dose (mg 8 hourly)**	**Vol (mL) needed with dilution of 125 mg/mL**	**Approx. single dose (mg 6 hourly)**	**Vol (mL) needed with dilution of 125 mg/mL**
4.5	40 mg	0.35 mL	30 mg	0.25 mL
9	75 mg	0.6 mL	55 mg	0.45 mL
13.6	115 mg	0.9 mL	85 mg	0.7 mL
18.1	150 mg	1.2 mL	115 mg	0.9 mL
22.7	190 mg	1.5 mL	140 mg	1.1 mL
Weight	**50 mg/kg day divided into 3 doses**		**25 mg/kg/day divided into 4 doses**	
Kg	**Approx. single dose (mg 8 hourly)**	**Vol (mL) needed With dilution of 225 mg/mL**	**Approx. single dose (mg 6 hourly)**	**Vol (mL) needed with dilution of 225 mg/mL**
4.5	75 mg	0.35 mL	55 mg	0.25 mL
9	150 mg	0.7 mL	110 mg	0.5 mL
13.6	225 mg	1 mL	170 mg	0.75 mL
18.1	300 mg	1.35 mL	225 mg	1 mL
22.7	375 mg	1.7 mL	285 mg	1.25 mL

In children with mild to moderate renal impairment (creatinine clearance of 70 to 40 mL/min), 60% of the normal daily dose given in divided doses every 12 hours should be sufficient. In children with moderate impairment (creatinine clearance of 40 to 20 mL/min), 25% of the normal daily dose given in divided doses every 12 hours should be sufficient. In children with severe impairment (creatinine clearance of 20 to 5 mL/min), 10% of the normal daily dose given every 24 hours should be adequate. All dosage recommendations apply after an initial loading dose is administered.

Since safety for use in premature infants and in infants under 1 month of age has not been established, the use of Cefazolin-AFT in these patients is not recommended.

Intraperitoneal administration

Intraperitoneal administration of cefazolin is usually well tolerated.

4.3 Contraindications

Hypersensitivity to the cephalosporin group of antibiotics or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

If an allergic reaction to Cefazolin-AFT occurs, the medicine should be discontinued and the patient treated with the usual agents e.g. adrenaline or other pressor amines, antihistamines, or corticosteroids.

Prolonged use of Cefazolin-AFT may result in the overgrowth of non-susceptible organisms. Careful

clinical observation of the patient is essential. If superinfection occurs during therapy, appropriate measures should be taken.

When Cefazolin-AFT is administered to patients with low urinary output because of impaired renal function, lower daily dosage is required.

The intrathecal administration of Cefazolin-AFT is not an approved route of administration for this antibiotic. There have been reports of severe central nervous system (CNS) toxicity including seizures when cefazolin was administered in this manner.

Broad spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.

Neurotoxicity

There have been reports of neurotoxicity associated with cephalosporin treatment. Symptoms of neurotoxicity include encephalopathy, seizures and/or myoclonus. Risk factors for developing neurotoxicity with cephalosporin treatment include being elderly, renal impairment, central nervous system disorders and intravenous administration. Withdrawal of the medicine should be considered if there are signs of neurotoxicity.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Mutagenicity studies and long-term studies in animals to determine the carcinogenic potential of Cefazolin-AFT have not been performed.

4.5 Interaction with other medicines and other forms of interaction

Used concurrently, probenecid may decrease renal tubular secretion of cephalosporins resulting in increased and more prolonged cephalosporin blood levels.

A false-positive reaction for glucose in the urine may occur with Benedict's solution, Fehling's solution, or CLINITEST Tablets, but not with enzyme-based tests, such as CLINISTIX and TES-TAPE. Positive direct and indirect antiglobulin (Coombs') tests have occurred; these may also occur in neonates whose mothers received cephalosporins before delivery.

Cefazolin-AFT should not be mixed in the syringe with aminoglycoside antibiotics.

4.6 Fertility, pregnancy and lactation

Use during Pregnancy and Lactation: Category B1.

Reproduction studies have been performed in rats given doses of 500 mg or 1 g of cefazolin/kg bodyweight and have revealed no evidence of impaired fertility or harm to the foetus due to cefazolin. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this medicine should be used during pregnancy only if clearly needed.

When Cefazolin-AFT has been administered prior to caesarean section, medicine levels in cord blood have been approximately one-fourth to one-third of maternal medicine levels. The medicine appears to have no adverse effect on the foetus.

Cefazolin-AFT is present in very low concentrations in the milk of nursing mothers. Caution should be exercised when Cefazolin-AFT is administered to a nursing woman.

4.7 Effects on ability to drive and use machines

This medicine is presumed to be safe or unlikely to produce an effect.

4.8 Undesirable effects

Tabulated list of adverse reactions:

Hypersensitivity:
Medicine fever, skin rash, vulvar pruritus, eosinophilia, Stevens-Johnson syndrome and anaphylaxis

Blood:
Neutropenia, leucopenia, thrombocytopenia, thrombocythaemia and positive direct and indirect Coombs' tests have occurred.

Renal:
Transient rise in BUN levels has been observed without clinical evidence of renal impairment. Interstitial nephritis and other renal disorders have been reported rarely. Most patients experiencing these effects have been seriously ill and were receiving multiple medicine therapies. The role of Cefazolin-AFT in the development of nephropathies has not been determined.

Hepatic:
Transient rise in AST, ALT, and alkaline phosphatase levels have been observed rarely. As with some penicillins and some other cephalosporins transient hepatitis and cholestatic jaundice have been reported rarely.

Gastrointestinal:
Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment. Nausea and vomiting have been reported rarely. Anorexia, diarrhoea and oral candidiasis (oral thrust) have been reported.

Other:
Pain on intramuscular injection, sometimes with induration, has occurred infrequently. Phlebitis at the site of injection has been noted. Other reactions have included genital and anal pruritus, genital moniliasis, and vaginitis.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https//nzphvc.otago.ac.nz/reporting/.

4.9 Overdose

Symptoms
Toxic signs and symptoms following an overdose of cefazolin may include pain, inflammation, and phlebitis at the injection site. The administration of inappropriately large doses of parenteral cephalosporins may cause dizziness, paresthesias, and headaches. Seizures may occur following overdosage with some cephalosporins, particularly in patients with renal impairment in whom accumulation is likely to occur.

Laboratory abnormalities that may occur after an overdose include elevations in creatinine, BUN, liver enzymes and bilirubin, a positive Coombs' test, thrombocytosis, thrombocytopenia, eosinophilia, leukopenia, and prolongation of the prothrombin time.

Treatment
In managing overdosage, consider the possibility of multiple medicine overdoses, interaction between medicines, and unusual medicine kinetics in your patient.

If seizures occur, the medicine should be discontinued promptly; anticonvulsant therapy may be administered if clinically indicated. Protect the patient's airway and support ventilation and perfusion. Meticulously monitor and maintain, within acceptable limits, the patient's vital signs, blood gases, serum electrolytes, etc.

In cases of severe overdosage, especially in a patient with renal failure, combined haemodialysis and haemoperfusion may be considered if response to more conservative therapy fails. However, no data supporting such therapy are available.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: First-generation cephalosporins ATC code: J01DB04

Mechanism of action

Cefazolin sodium is a semisynthetic cephalosporin for intramuscular or intravenous administration. In vitro tests demonstrate that the bactericidal action of cephalosporins results from inhibition of cell-wall synthesis.

Cefazolin is active against the following organisms *in vitro* and in clinical infections:

- *Staphylococcus aureus* (including penicillinase-producing strains),
- Staphylococcus epidermidis.
- Group A β-haemolytic streptococci and other strains of streptococci (many strains of enterococci are resistant).
- *Streptococcus pneumoniae*
- *Escherichia coli*
- *Klebsiella sp*.
- *Proteus mirabilis*
- Haemophilus influenzae
- *Enterobacter aerogenes*
- Most strains of indole-positive Proteus (Proteus vulgaris), *Enterobacter cloacae*, *Morganella morganii*, and *Providencia rettgeri* are resistant.
- Methicillin-resistant staphylococci, Serratia, Pseudomonas and Acinetobacter calcoaceticus (formerly Mima and Herellea sp.) are almost uniformly resistant to cefazolin.

Disc Susceptibility Tests:

Quantitative methods that require measurements of zone diameters give the most precise estimates of antibiotic susceptibility. One such procedure has been recommended for use with discs for testing susceptibility to cefazolin. With this procedure, a report from the laboratory of "susceptible" indicates that the infecting organism is likely to respond to therapy. A report of "resistant" indicates that the infecting organism is not likely to respond to therapy. A report of "moderately susceptible" suggests that the organism would be susceptible if high dosage is used or if the infection were confined to tissues and fluids (e.g. urine) in which high antibiotic levels are attained.

For gram-positive isolates, a zone of 18 mm is indicative of a cefazolin-susceptible organism when tested with either the cephalosporin-class disc (30 mcg cephalothin) or the cefazolin disc (30 mcg cefazolin).

Gram-negative organisms should be tested with the cefazolin disc (using the above criteria) because cefazolin has been shown by in vitro tests to have activity against certain strains of Enterobacteriaceae found to be resistant when tested with the cephalothin disc. When using the cephalothin disc, Gram-negative

organisms with zone diameters >18 mm may be considered susceptible to cefazolin however organisms with zone diameters < 18 mm are not necessarily resistant or moderately susceptible to cefazolin.

The cefazolin disc should not be used for testing susceptibility to other cephalosporins.

Dilution Techniques:

A bacterial isolate should be considered susceptible if the minimal inhibitory concentration (MIC) for cefazolin is < 16 mcg/mL. Organisms are considered resistant if the MIC is > 64 mcg/mL.

5.2 Pharmacokinetic properties

Table 4 demonstrates the blood levels and duration of cefazolin following intramuscular administration.

Table 4 – Serum concentrations after intramuscular administration.

Dose	Serum Concentrations (mcg/mL)					
	½ Hr	1 Hr	2 Hr	4 Hr	6 Hr	8 Hr
250 mg	15.5	17	13	5.1	2.5	
500 mg	36.2	36.8	37.9	15.5	6.3	3
1 g*	60.1	63.8	54.3	29.3	13.2	7.1

* Average of 2 studies

Clinical pharmacology studies in patients hospitalised with infections indicate that cefazolin produces mean peak serum levels approximately equivalent to those seen in normal volunteers.

In a study (using normal volunteers) of constant intravenous infusion with dosages of 3.5 mg/kg for 1 hour (approximately 250 mg) and 1.5 mg/kg for the next 2 hours (approximately 100 mg), cefazolin produced a steady serum level at the third hour of approximately 28 mcg/mL.

Table 5 shows the average serum concentrations after IV injection of a single 1g dose: average half-life was 1.4 hours.

Table 5 – Serum concentrations after 1g intravenous dose.

Serum Concentration (mcg/mL)					
5 min	15 min	30 min	1 Hr	2 Hr	4 Hr
188.4	135.8	106.8	73.7	45.6	16.5

Controlled studies in adult normal volunteers receiving 1 g, 4 times a day, for 10 days, monitoring CBC, AST, ALT, bilirubin, alkaline phosphatase, BUN, creatinine, and urinalysis indicated no clinically significant changes attributed to cefazolin.

Cefazolin is excreted unchanged in the urine primarily by glomerular filtration and, to a lesser degree, by tubular secretion. Following intramuscular injection of 500mg, 56% to 89% of the administered dose is recovered within 6 hours, and 80% to nearly 100% in 24 hours. Cefazolin achieves peak urine concentrations greater than 1000 mcg/mL and 4000 mcg/mL, respectively, following 500 mg and 1 g intramuscular doses.

In patients undergoing peritoneal dialysis (2 L/hr) mean serum levels of cefazolin were approximately 10 and 30 mcg/mL after 24 hours' instillation of a dialysing solution containing 50 mcg/mL and 150 mcg/mL, respectively. Mean peak levels were 29 mcg/mL (range 13-44 mcg/mL) with 50 mcg/mL (3 patients), and 72 mcg/mL (range 26-142 mcg/mL) with 150 mcg/mL (6 patients). Intraperitoneal administration of cefazolin is usually well tolerated.

When cefazolin is administered to patients with unobstructed biliary tracts, high concentrations well above serum levels occur in the gall-bladder tissue and bile. In the presence of obstruction, however, concentration of the antibiotic is considerably lower in bile than the serum.

Cefazolin readily crosses an inflamed synovial membrane, and the concentration of the antibiotic achieved in the joint space is comparable to levels measured in the serum.

Cefazolin readily crosses the placental barrier into the cord blood and amniotic fluid. It is present in very low concentrations in the milk of nursing mothers.

5.3 Preclinical safety data

Before Cefazolin-AFT therapy is instituted, careful inquiry should be made concerning previous hypersensitivity reactions to cephalosporins and penicillin. Cephalosporin C derivatives should be given cautiously to penicillin- sensitive patients. Serious acute hypersensitivity reactions may require adrenaline and other emergency measures.

There is some clinical and laboratory evidence of partial cross-allergenicity between the penicillins and the cephalosporins. Patients have been reported to have had severe reactions (including anaphylaxis) to both medicines.

Antibiotics, including Cefazolin-AFT should be administered cautiously to any patient who has demonstrated some form of allergy, particularly to medicines.

Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics (including macrolides, semisynthetic penicillins, and cephalosporins). It is important to consider its diagnosis in patients who develop diarrhoea in association with the use of antibiotics. Such colitis may range in severity from mild to life threatening. In moderate to severe cases, appropriate measures should be taken.

Usage in Infants:

Safety for use in premature infants and infants under one month of age has not been established.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None.

6.2 Incompatibilities

Cefazolin is incompatible with amikacin disulfate, amobarbital-sodium, bleomycin sulphate, calcium gluceptate, calcium gluconate, cimetidin hydrochloride, colistin methat-sodium, erythromycin gluceptate, kanamycin sulphate, oxytetracyclin hydrochloride, pentobarbital-sodium, polymyxin-B- sulphate and tetracycline hydrochloride.

This medicinal product must not be mixed with other medicinal products except those mentioned in section 4.2.

6.3 Shelf life

Cefazolin-AFT 500 mg: 24 months.

Cefazolin-AFT 1 g: 24 months in type I glass vials and 30 months in type II glass vials.

Cefazolin-AFT 2 g: 24 months.

In those situations in which the medicine and the diluent have been mixed, but not immediately administered to the patient, the admixture may be stored under the following conditions: Reconstituted Cefazolin-AFT diluted in Sterile Water for Injection, 5% Dextrose Injection, 0.9% Sodium Chloride Injection, or Bacteriostatic Water for Injection is stable for 12 hours at room temperature and for 24 hours if stored

under refrigeration (2-8°C).

Solutions of Cefazolin-AFT in 10% Dextrose Injection, 5% Dextrose in Lactated Ringer's Injection, 5% Dextrose and 0.9% Sodium Chloride Injection (also may be used with 5% Dextrose and 0.45% or 0.2% Sodium Chloride Injection), Lactated Ringer's Injection, 5% or 10% Invert Sugar in Sterile Water for Injection, Ringer's Injection, Normosol-M in D5-W, Ionosol-B with Dextrose 5%, or Plasma-Lyte with 5% Dextrose should be used within 12 hours after dilution if stored at room temperature or within 24 hours if stored under refrigeration (2-8°C). Do not freeze reconstituted Cefazolin-AFT.

6.4 Special precautions for storage

Cefazolin-AFT 500 mg and 1 g: Store below 25°C.

Cefazolin-AFT 2 g: Store below 30°C.

For storage conditions after reconstitution, see section 6.3.

6.5 Nature and contents of container

Cefazolin-AFT is supplied in type I (500 mg and 1 g) or type II glass vials (500 mg, 1 g and 2 g) sealed with film-coated butyl rubber stopper.

Packs of 1, 5 and 10 vials.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

To reduce microbiological hazards, use as soon as practicable after reconstitution. Cefazolin-AFT does not contain any anti-microbial agents and is intended for single use in one patient only. Discard any residue. Prior to administration, parenteral medicine products should be inspected visually for particulate matter and discolouration whenever solution and container permit.

7 MEDICINE SCHEDULE

Prescription medicine

8 SPONSOR

AFT Pharmaceuticals Ltd
PO Box 33203 Takapuna
Auckland
Email: customer.service@aftpharm.com

9 DATE OF FIRST APPROVAL

4 May 2017

10 DATE OF REVISION OF THE TEXT

16-02-2023

SUMMARY TABLE OF CHANGES

Version	Date	Change
4.4	16-02-2023	Added neurotoxicity warnings