NEW ZEALAND DATA SHEET

1. PRODUCT NAME

Cefoxitin Actavis, Powder for Injection 1g and 2g

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial contains cefoxitin sodium equivalent to 1 g or 2 g of cefoxitin.

Each gram of cefoxitin sodium contains approximately 51.2 mg (2.2 mEq) of sodium. The pH of 10% w/v cefoxitin sodium in Water for Injections is 4.2 to 7.0.

3. PHARMACEUTICAL FORM

Cefoxitin Actavis is a white to slightly yellow sterile powder of cefoxitin sodium for intravenous and intramuscular administration following reconstitution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Cefoxitin Actavis is indicated for the treatment of the following infections when due to susceptible organisms (see **Microbiology)** peritonitis and other intra-abdominal and intra-pelvic infections, female genital tract infections, septicaemia, endocarditis, urinary tract infections, respiratory tract infections, bone and joint infections, skin and skin structure infections. Cefoxitin Actavis has a high degree of stability against ß-lactamase and is therefore effective against ß-lactamase producing organisms resistant to penicillins or cephalosporins. It can also be used in mixed infections provided that the organisms are sensitive to it.

Cefoxitin Actavis can be used as adjunctive therapy in the surgical treatment of infections including abscesses, infection complicating hollow viscus perforations, cutaneous infections and infections of serous surfaces whether caused by aerobes, mixed aerobes and anaerobes, or anaerobes.

Cefoxitin Actavis is also indicated for the prevention of post-operative infections associated with certain surgical procedures of the gastrointestinal, biliary and genital tracts.

4.2 Dose and method of administration

Treatment

Cefoxitin Actavis may be administered intravenously or intramuscularly (see reconstitution directions for each route below). Dosage and route of administration are determined by severity of infection, susceptibility of the causative organisms, and condition of the patient.

Therapy may be started while awaiting the results of susceptibility testing.

Adults: The usual adult dosage is 1 g or 2 g of cefoxitin sodium every 8 hours (see chart). In adults with renal insufficiency, an initial loading dose of 1 g to 2 g may be given. After a loading dose, the recommendations for maintenance dosage may be used as a guide.

In severe infections, the total daily dosage should not exceed 12 g per day.

Guidelines for dosage of Cefoxitin Actavis

Type of Infection	Dose	Frequency	Total Daily Dosage
Uncomplicated	1 g	Every 8 hours (occasionally every 6 hours)	3 g (4 g)
Moderately severe or severe	2 g	Every 8 hours (occasionally every 6 hours)	6 g (8 g)
Infections generally needing antibiotics in higher dosage	3 g (2 g)	Every 6 hours (Every 4 hours)	12 g

Maintenance dosage of Cefoxitin Actavis in adults with reduced renal function

Renal function	Creatinine Clearance (mL/min)	Dose	Frequency
Mild impairment	80-30	1-2 g	Every 8-12 hours
Moderate impairment	29-10	1-2 g	Every 12-24 hours
Severe impairment	<10	0.5-1 g	Every 12-24 hours
Patients on dialysis*	<5	0.5-1 g	Every 24-48 hours

*In patients undergoing haemodialysis, the loading dose of 1 to 2 g should be given after each haemodialysis, and the maintenance dose should be given as indicated in the table above. Monitoring of plasma levels is advised.

Uncomplicated gonorrhoea

For single dose therapy of uncomplicated gonorrhoea, including that caused by penicillinase-producing strains, the recommended dose is 2 g of cefoxitin sodium intramuscularly given with 1g of probenecid by mouth (at the same time or up to 1 hour before).

Neonates, infants and children

Neonates: 0 to1 week of age, 20 to 40 mg/kg every 12 hours. 1 to 4 weeks of age, 20 to 40 mg/kg every 8 hours.

Dosage for premature infants not yet established.

Infants: (1 to 3 months) 20 to 40 mg/kg every 6 hours or every 8 hours.

Children: (over 3 months) 20 to 40 mg/kg every 6 hours or every 8 hours.

Cefoxitin sodium is not recommended for the therapy of meningitis. If meningitis is suspected, an appropriate antibiotic should be used.

In children with renal insufficiency, the dosage frequency should be reduced as indicated for adults.

Prophylaxis

For prophylactic use, the following doses are recommended:

Adults: 2 g administered intramuscularly approximately 1 hour before initial incision or intravenously just prior to surgery; then 2 g repeated twice at 6 hourly intervals.

Neonates, infants and children: There are no paediatric data on the prophylactic use of cefoxitin sodium. However, in view of its human efficacy and safety in this age group, the following doses are proposed - in the case of infants and children 30 to 40 mg/kg doses may be given at the times designated above. However, in neonates 30 to 40 mg/kg doses may be given approximately 1 hour before initial incision and one further dose may be given after 8 to 12 hours.

Caesarean section patients: The first dose of 2.0 g is administered intravenously as soon as the umbilical cord has been clamped. The second and third doses should be given as 2.0 g intravenously or intramuscularly 4 hours and 8 hours after the first dose.

Administration

Intravenous administration

Warning For Neonates: Solutions containing preservatives should not be used for injection or for flushing catheters in treating neonates. Benzyl alcohol as a preservative in Bacteriostatic Water for Injections has been associated with toxicity in neonates. Data are unavailable on the toxicity of other preservatives in this age group. Therefore, any diluent used with Cefoxitin Actavis in the treatment of neonates should be free of any preservative.

Reconstitution

Reconstitute Cefoxitin Actavis with Sterile Water for Injections - 1 g is soluble in 2 mL. Although cefoxitin sodium is very soluble, for intravenous use it is preferable to add 10mL of Sterile Water for Injections to the 1 g vial or 10 mL to 20 mL to the 2 g vial. Shake to dissolve and then withdraw entire contents of the vial into a syringe.

For direct intravenous injection, cefoxitin sodium may be slowly injected into the vein over a period of 3 to 5 minutes or may be given through the tubing when the patient is receiving compatible parenteral solutions.

Alternatively, an intermittent intravenous infusion of cefoxitin sodium may be employed when large amounts of fluid are to be given. However, during infusion of the solution containing cefoxitin sodium, it may be advisable temporarily to discontinue administration of any other infusion solution at the same site (by using an appropriate IV infusion set).

A solution of cefoxitin sodium may also be given by continuous intravenous infusion (see **Compatibility information).**

Intramuscular administration

Reconstitute Cefoxitin Actavis 1 g with 2 mL of 0.5 percent or 1 percent lignocaine hydrochloride (without adrenaline) solution. Some patients may be hypersensitive to lignocaine (see **Undesirable Effects**)

If lignocaine cannot be used, Cefoxitin Actavis may be reconstituted with 2 mL of Sterile Water for Injections. The 2 g vial may be reconstituted with 4 mL of diluent for intramuscular use. Cefoxitin sodium is given by deep injection into a large muscle mass. Avoid injection into a blood vessel.

Preparation of Solution

The following table is provided for convenience in reconstituting Cefoxitin Actavis for both intravenous and intramuscular administration.

Strength	**Amount of Diluent to be Added (mL*)**	**Approximate Average Concentration (mg/mL)**
1 g vial	2 (IM)	400
1 g vial	10 (IV)	95
2 g vial	10 or 20 (IV) 4 (IM)	180 or 95 400

* Shake to dissolve and let stand until clear.

Product is for single use in one patient only.

Compatibility information
The compatibility and stability of cefoxitin sodium in solution with the following series of frequently used intravenous infusion fluids and injectable additives have been established:

Sodium Chloride Intravenous Infusion 0.9%, Glucose Intravenous Infusion 5% or 10%, Glucose 5% with Sodium Chloride Intravenous Infusion 0.9%, Lactated Ringers Injection, Glucose 5% in Lactated Ringers Injection, Invert sugar 5% or 10% in water, Heparin 100 units/mL in Glucose 5% or Sodium Chloride Intravenous Infusion.

Cefoxitin Actavis reconstituted to a concentration of 95mg/mL or 400mg/mL with Water for Injections, or Water for Injections preserved with benzyl alcohol, or Sodium Chloride Intravenous Infusion 0.9%, or Glucose Intravenous Infusion 5% strength or 10% strength should be used immediately after preparation. Any unused portion should be discarded.

The reconstituted solutions maintain satisfactory chemical potency for 6 hours at 30 °C and for 96 hours at 2 to 8°C.

More dilute solutions of cefoxitin 1 mg/mL or 40 mg/mL in Water for Injections, or Sodium Chloride Intravenous Infusion 0.9%, or Glucose Intravenous Infusion 5% strength or 10% strength, or Glucose 5% strength with Sodium Chloride Intravenous Infusion 0.9%, or Glucose 5% strength in Lactated Ringers Injection, or Lactated Ringers Injection, or Invert Sugar 5% strength or 10% strength in Water for Injections, or Heparin 100u/mL in Glucose Intravenous Infusion 5% strength or Sodium Chloride Intravenous Infusion 0.9% should be used immediately after preparation. Any unused portion should be discarded.

The reconstituted solutions retain adequate potency for up to 6 hours when stored at 30°C and for at least 36 hours when stored at 2 to 8°C.

4.3 Contraindications
Cefoxitin Actavis is contraindicated in patients who have had previous experience of a major allergy or anaphylaxis to a cephalosporin or penicillin.

Its use in patients with a history of hypersensitivity to penicillin requires great care (see **Special warnings and precautions for use**). Cefoxitin Actavis is contraindicated in patients who have had a major allergic reaction to penicillin (anaphylaxis, angioneurotic oedema or urticaria).

Lignocaine hydrochloride should not be used as a diluent for intramuscular injection in patients who are hypersensitive to lignocaine.

4.4 Special warnings and precautions for use

There is some clinical and laboratory evidence of partial cross-allergenicity between cephamycins and the other ß-lactam antibiotics, penicillins and cephalosporins. Severe reactions (including anaphylaxis) have been reported with most beta-lactam antibiotics.

Cefoxitin Actavis should be given with caution to patients who have experienced symptoms of allergy associated with a cephalosporin or penicillin. Serious hypersensitivity reactions may require ADRENALINE (EPINEPHRINE) and other emergency measures.

Neonates: Solutions containing preservatives should not be used for injection or for flushing catheters in treating neonates. Benzyl alcohol as a preservative in Bacteriostatic Water for Injections has been associated with toxicity in neonates. Data are unavailable on the toxicity of other preservatives in this age group. Therefore, any diluent used with Cefoxitin Actavis in the treatment of neonates should be free of any preservative.

The total daily dosage should be reduced when Cefoxitin Actavis is administered to patients with transient or persistent reduction of urinary output due to renal insufficiency (see **Dose and method of administration**) because high and prolonged serum antibiotic concentrations can occur from usual doses.

Concentrations of cefoxitin sodium in the CSF are considerably lower than in the plasma. Its use in the treatment of meningitis and brain abscess is therefore not advised.

Superinfection with non-susceptible organisms, including fungi, may occur and requires appropriate therapy.

Cefoxitin sodium appears to have little nephrotoxic potential in man at the usual doses. Patients whose clinical condition requires high doses, especially when potentially nephrotoxic drugs (eg aminoglycoside antibiotics) are administered concurrently, should be carefully monitored for renal function. Increased nephrotoxicity has been reported following concomitant administration of cephalosporins and aminoglycoside antibiotics.

Repeated use of lignocaine hydrochloride as a diluent for intramuscular use should be avoided in patients with severe liver disease or decreased hepatic blood flow, due to the possibility of lignocaine toxicity (resulting from decreased metabolism and accumulation).

***Clostridium difficile* associated diarrhoea (CDAD)**

Clostridium difficile associated diarrhoea (CDAD) has been reported with nearly all antibacterial agents, including cefoxitin injection and may range in severity from mild diarrhoea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *C. difficile.*

Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics. It is important to consider this diagnosis in patients who develop diarrhoea in association with the use of Cefoxitin Actavis. Drugs which delay peristalsis may prolong and/or worsen the condition and should not be used..

Toxin produced by *Clostridium difficile*, appears to be the primary cause. Hypertoxin producing strains of *C.difficile* cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhoea following antibiotic use. It is important to consider this diagnosis in patients who develop diarrhoea or colitis in association with antibiotic use (this may occur up to several weeks -usually over two months after cessation of antibiotic therapy). Mild cases usually respond to drug discontinuation alone. However, in moderate to severe cases appropriate therapy with a suitable oral antibacterial agent effective against *Clostridium difficile* should be considered. Fluids, electrolytes and protein replacement should be provided when indicated.

Antibiotics should be prescribed with care for patients with a history of gastrointestinal disease, especially ulcerative colitis, regional enteritis, or antibiotic associated colitis.

Prolonged prothrombin time may occur in patients receiving protracted antimicrobial therapy.

Use in patients with impaired renal function
This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. The total daily dosage should be reduced when Cefoxitin Actavis is administered to patients with transient or persistent reduction of urinary output due to renal impairment, because high and prolonged serum antibiotic concentrations can occur in such individuals. (see **Dose and method of administration**).

Elderly patients are more likely to have decreased renal function, care should be taken in dose selection and it may be useful to monitor renal function.

4.5 Interaction with other medicines and other forms of interaction

Interactions with other drugs
Cephalosporins have affected the stability of anticoagulant control of patients treated with phenindione and warfarin during one trial.

Concurrent treatment with nephrotoxic drugs such as gentamicin and frusemide may result in increased nephrotoxicity (see **Special warnings and precautions for use**).

Concomitant administration of oral probenecid competitively inhibits tubular secretion resulting in higher and more prolonged serum concentrations of cefoxitin.

Interference with laboratory tests
A false-positive reaction to glucose in the urine may occur with reducing substances but not with the use of specific glucose oxidase methods.

Using the Jaffe Technique, falsely high creatinine values in serum may occur if cefoxitin sodium serum concentrations exceed 100 micrograms/mL. Serum samples from patients treated with cefoxitin sodium should not be analysed for creatinine if withdrawn within two hours of drug administration.

High concentrations of cefoxitin in the urine may interfere with measurement of 17-hydroxy-corticosteroids by the Porter-Silber reaction, and produce false increases of modest degree in the levels reported.

4.6 Fertility, pregnancy and lactation

Pregnancy Category B1. This category specifies drugs which have been taken by only a limited number of pregnant women and women of child-bearing age, without an increase in the frequency of malformations or other direct or indirect harmful effects on the human foetus having been observed.

Studies in animals have not shown evidence of an increased occurrence of foetal damage. Cefoxitin Actavis should not however be used in women of childbearing potential unless, in the judgement of the treating clinician, its use is deemed essential to the welfare of the patient and the expected benefits outweigh potential risks.

Cefoxitin sodium is excreted in human milk. If possible, alternative arrangements should be made to feed the infant.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

Cefoxitin sodium is generally well tolerated. Adverse effects occurred in 8.5% of cases, were usually mild and transient, and rarely required cessation of treatment.

Local reactions

Thrombophlebitis or phlebitis has occurred in 2.5% of cases following intravenous administration. Another 1.7% of cases reported pain in the infused vein and vein induration, erythema or exudates.

Pain, induration and tenderness following intramuscular injections have been reported. Pain was often severe in cases where Cefoxitin Actavis had been dissolved in Water for Injections instead of 0.5% lignocaine hydrochloride (see **Dose and method of administration).**

Allergic

Skin rashes, eg. maculopapular rash and urticaria, occurred in 1.7% of cases. Other adverse effects included cutaneous vasculitis, pruritus, eosinophilia, fever and, rarely, other allergic reactions, including anaphylaxis, which in rare cases has led to death.

Gastrointestinal

Nausea, vomiting and diarrhoea have been reported rarely (see **Special warnings and precautions for use).**

Cardiovascular

Hypotension.

Blood

Eosinophilia, leukopenia, agranulocytosis, granulocytopenia, neutropenia, thrombocytopenia, haemolytic anaemia and bone marrow depression have been reported. Some individuals, particularly those with azotaemia, may develop positive direct Coombs tests during therapy with cefoxitin sodium.

Liver function

Transient elevations in AST, ALT, serum LDH, and serum alkaline phosphatase have been reported. Jaundice has occurred.

Renal and urinary disorders
Elevations in serum creatinine and/or blood urea nitrogen levels have been observed. As with the cephalosporins, acute renal failure has been reported rarely. The role of cefoxitin sodium in changes in renal function tests is difficult to assess, since factors predisposing to prerenal azotaemia or to impaired renal function usually have been present.

Other
In addition to the adverse reactions listed above which have been observed in patients treated with cefoxitin, the following adverse reactions and altered laboratory test results have been reported for cephalosporins class antibiotics:

Urticaria, erythema multiforme, Stevens-Johnson syndrome, serum sickness-like reactions, abdominal pain, colitis, renal dysfunction, toxic nephropathy, false positive test for urinary glucose, hepatic dysfunction including cholestasis, elevated bilirubin, aplastic anaemia, haemorrhage, prolonged prothrombin time, pancytopenia, agranulocytosis, superinfection, vaginitis including vaginitis candidiasis.

Several cephalosporins have been implicated in triggering seizures, particularly in patients with renal impairment when the dosage was not reduced (see **Dose and method of administration).** If seizures associated with drug therapy occur, the drug should be discontinued. Anticonvulsant therapy can be given if clinically indicated.

4.9 Overdose
Expected effects would be those described under **Undesirable Effects;** namely, Allergic, Gastrointestinal, Blood, Liver function and Kidney.

In case of overdose, immediately contact the Poisons Information Centre for advice, call 0800 764 766.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Cefoxitin is a bactericidal antibiotic which acts by inhibiting bacterial cell wall synthesis. Due to the presence of a 7- a methoxy group in the ß-lactam ring, it exhibits a high degree of stability in the presence of beta-lactamases.

Microbiology
Cefoxitin is active against the following microorganisms *in vitro:*

Aerobic bacteria

1. Gram-positive cocci including *Staphylococci* (including coagulase-positive, coagulase negative and penicillinase producing strains), Group A beta-haemolytic streptococci *(Streptococcus pyogenes),* Group B beta-haemolytic streptococci *(Streptococcus agalactiae)* and Streptococcus pneumoniae *(Diplococcus pneumoniae).* Other streptococci (most strains of enterococci, eg *Streptococcus faecalis)* are resistant.

2. Gram-negative cocci including *Neisseria gonorrhoeae* (including penicillinase-producing strains) and *Neisseria meningitidis.*

3. Gram-negative rods (facultative anaerobes) including *Escherichia coli, Klebsiella pneumoniae,* Klebsiella spp, *Proteus mirabilis, Proteus* (indole-positive), *Proteus vulgaris, Providencia rettgeri, Morganella morganii, Serratia marcescens ,* Providencia spp, Salmonella and Shigella spp

Anaerobic bacteria

1. Gram-positive cocci including Peptococcus spp, Peptostreptococcus spp and Microaerophilic streptococcus.

2. Gram-positive rods including *Clostridium perfringens*, Clostridium spp, Eubacterium spp and *Propionibacterium acnes.*

3. Gram-negative cocci including Veillonella spp

4. Gram-negative rods including *Bacteroides fragilis, Bacteroides melaninogenicus,* Bacteroides spp (including both penicillin-susceptible and penicillin-resistant strains) and Fusobacterium spp

Cefoxitin sodium is not active against pseudomonas spp, most strains of enterococci and many strains of *Enterobacter cloacae.* Methicillin-resistant staphylococci are almost uniformly resistant to cefoxitin sodium.

Susceptibility testing

For fast-growing aerobic organisms, quantitative methods that require measurements of zone diameters give the most precise estimates of antibiotic susceptibility. One such procedure (Kirby-Bauer) has been recommended for use with discs to test susceptibility to cefoxitin. Interpretation involves correlation of the diameters obtained in the disc test with minimal inhibitory concentration (MIC) values for cefoxitin sodium.

Reports from the laboratory giving results of the standardized single disc susceptibility test using a 30 microgram cefoxitin disc should be interpreted according to the following criteria:

Organisms producing zones of 18 mm or greater are considered susceptible indicating that the tested organism is likely to respond to therapy.

Organisms of intermediate susceptibility produce zones of 15 to 17 mm indicating that the tested organism would be susceptible if high dosage is used or if the infection is confined to tissues and fluids (eg urine) in which high antibiotic levels are attained.

Resistant organisms produce zones of 14 mm or less indicating that other therapy should be selected.

The cefoxitin disc should be used for testing cefoxitin susceptibility.

Cefoxitin sodium has been shown by *in vitro* tests to have activity against certain strains of *Enterobacteriaceae* found resistant when tested with the cephalosporin class disc. For this reason, the cefoxitin disc should not be used for testing susceptibility to cephalosporins, and cephalosporin discs should not be used for testing susceptibility to cefoxitin sodium.

Dilution methods, preferably the agar plate dilution procedure, are most accurate for susceptibility testing of obligate anaerobes. A bacterial isolate may be considered susceptible if the MIC value for cefoxitin sodium is not more than 16 micrograms/mL. Organisms are considered resistant if the MIC is greater than 32 micrograms/mL.

Dilution or diffusion techniques – either quantitative (MIC) or breakpoint, should be used following a regularly updated, recognised and standardised method (e.g. Clinical and Laboratory Standards Institute (CLSI)). Standardised susceptibility test procedures require the use of laboratory control microorganisms to control the technical aspects of the laboratory procedures.

A report of "Susceptible" indicates that the pathogen is likely to be inhibited if the antimicrobial compound in the blood reaches the concentrations usually achievable.

A report of “Intermediate” indicates that the result should be considered equivocal, and if the microorganisms not fully susceptible to alternative, clinically feasible drugs, the test should be repeated. This category implies possible clinical applicability in body sites where the drug is physiologically concentrated or in situations where high dosage of drug can be used. This category also requires a buffer zone, which prevents small-controlled technical factors causing major discrepancies in interpretation.

A report of “Resistant” indicates that the pathogen is not likely inhibited if the antimicrobial compound in the blood reaches concentrations usually achievable; other therapy should be selected.

Note: The prevalence of resistance may vary geographically for selected species and local information in resistance is desirable, particularly when treating severe infections.

5.2 Pharmacokinetic properties

Cefoxitin sodium administered by the parenteral route is excreted virtually unchanged by the kidneys. The mean terminal serum half-life is approximately one hour and co-administration of probenecid will slow tubular excretion and increase and prolong blood levels. Although cefoxitin sodium will penetrate into the CSF, concentrations are considerably lower than in the plasma.

Following **intravenous administration,** the peak serum concentration of cefoxitin sodium following 1g infused intravenously over 3 minutes was 110.5 micrograms/mL, when infused over 30 minutes was 72 micrograms/mL, and when infused over 120 minutes was 25 micrograms/mL. Following 2 g infused intravenously over 3 minutes, the peak serum concentration was 221 micrograms/mL. The serum half-life was approximately 50 minutes, falling to less than 1 microgram/mL at 4 hours.

In a number of studies using 0.5 g, 1 g, or 2 g intravenous doses of cefoxitin sodium, mean total urinary recovery ranged from 77 percent to 99 percent of the dose administered.

Following **intramuscular administration,** injections of 1 g of cefoxitin sodium in 0.5 percent lignocaine hydrochloride solution produced a peak serum concentration of approximately 30 micrograms/mL at 30 minutes, falling to approximately 3.2 micrograms/mL at 3 hours. Approximately 85percent of an intramuscular dose is excreted by the kidneys in the first six hours resulting in high urine levels; for example, greater than 3000 micrograms/mL between one and two hours after a 1 g dose. When Cefoxitin Actavis was reconstituted with 0.5 percent or 1 percent of lignocaine hydrochloride for intramuscular use, the local anaesthetic was found to have no effect on the absorption or elimination.

5.3 Preclinical safety data

Studies in animals have not shown evidence of an increased occurrence of foetal damage. Cefoxitin Actavis should not however be used in women of childbearing potential unless, in the judgement of the treating clinician, its use is deemed essential to the welfare of the patient and the expected benefits outweigh potential risks.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None

6.2 Incompatibilities
Refer to **Dosage and Administration, *Preparation of solution.***

6.3 Shelf life
36 months from date of manufacture stored at or below 25°C protect from light.
36 hours reconstituted stored at 2° to 8°C (Refrigerate, do not freeze)
6 hours reconstituted stored at or below 30°C protect from light

6.4 Special precautions for storage
Store below 25°C. Protect from light.

For storage of reconstituted vials please refer to "**Compatibility Information"** section.

6.5 Nature and contents of container

Strength	*Pack Size*
Cefoxitin Actavis equivalent to 1 g	5 vials and 10 vials
Cefoxitin Actavis equivalent to 2 g	5 vials and 10 vials

Not all pack sizes may be marketed

6.6 Special precautions for disposal
No special requirements for disposal. Any unused medicine or waste material should be disposed of in accordance with local requirements.

7. MEDICINE SCHEDULE
Prescription Medicine.

8. SPONSOR
Teva Pharma (New Zealand) Limited
PO Box 128 244
Remuera
Auckland 1541
Telephone: 0800 800 097

9. DATE OF FIRST APPROVAL
11th May 1995

10. DATE OF REVISION OF THE TEXT
08th March 2017

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
	-Updated to SPC style format as per Medsafe's data sheet consultation. -Sponsor name changed from Actavis New Zealand Limited to Teva Pharma (New Zealand) Ltd -Sponsor address changed from street address to P.O box address -Telephone number changed to 0 800 800 097