

Cefotaxime Sandoz

Cefotaxime Sodium Ph Eur, powder for injection, 500 mg, 1 g and 2 g (as cefotaxime)

Presentation

Cefotaxime Sandoz powder for injection is a white to slightly yellowish powder aseptically filled into glass vials.

Cefotaxime Sandoz 500 mg contains in a 15 ml vial, sterile Cefotaxime Sodium Ph Eur equivalent to cefotaxime 500 mg.

Cefotaxime Sandoz 1 g contains in a 20 ml vial, sterile Cefotaxime Sodium Ph Eur equivalent to cefotaxime 1 g.

Cefotaxime Sandoz 2 g contains in a 20 ml or 50 ml vial, sterile Cefotaxime Sodium Ph Eur equivalent to cefotaxime 2 g.

Uses

Actions

Pharmacotherapeutic group

J01DD01 - Third generation cephalosporins, cefotaxime.

Mechanism of action

Beta-lactam antibiotic.

Pharmacodynamic effects

Inhibition of bacterial cell wall synthesis.

Onset and duration of action

The duration of treatment depends on the patient's response and therapy should be continued for at least three days after body temperature normalisation.

Antibiotic class

Cefotaxime is a semisynthetic broad spectrum bactericidal cephalosporin antibiotic for parenteral use.

Antibiotic nature and mode of action

Cefotaxime is exceptionally active *in-vitro* against Gram-negative organisms sensitive or resistant to first or second generation cephalosporins. It is similar to other cephalosporins in activity against Gram-positive bacteria.

Cefotaxime has been used with other beta-lactam antibiotics such as carbenicillin in the treatment of neutropenic patients.

Cefotaxime Sandoz may also be administered with metronidazole in the treatment of mixed infections caused by anaerobic and aerobic organisms.

Susceptibility data

Dilution or diffusion techniques – either quantitative minimum inhibitory concentrations (MIC) or breakpoint, should be used following a regularly updated, recognised and standardised method (e.g. NCCLS). 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 microorganism is 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 provides a buffer zone, which prevents small uncontrolled technical factors from causing major discrepancies in interpretation.

The following lists describe the spectrum of cefotaxime activity under *in vivo* conditions at plasma concentrations achieved with the recommended doses.

Gram-positive pathogens

Susceptible micro-organisms include: *Staphylococci* spp, including penicillinase-producing strains; methicillin susceptible *Staphylococcus aureus* (15% non-susceptible); *Streptococcus pneumoniae*; *Streptococcus pyogenes*.

Resistant micro-organisms include: methicillin resistant *Staphylococci*; *Enterococcus faecalis*; *Clostridium perfringens*.

Gram-negative pathogens

Various strains of *Klebsiella*, *Enterobacter* and *Serratia*; *Escherichia coli* (0.1% non-susceptible) including many gentamicin and cephalothin-resistant strains; *Haemophilus influenzae* (0.3% non-susceptible); *Proteus* genera (including *P. vulgaris*, *P. rettgeri*, *P. mirabilis* (2.6% non-susceptible) and *P. morgani*); *Neisseria* spp.; Gonococcus including penicillin-resistant strains;

Resistant micro-organisms include: *Enterobacter cloacae* (39.6% non-susceptible).

Resistance

A report of "Resistant" indicates that the pathogen is not likely to be inhibited if the antimicrobial compound in the blood reaches the concentrations usually achievable, other therapy should be selected. Cefotaxime also shows resistance to many beta-lactamases (penicillinases and cephalosporinases).

Clinically relevant MIC ranges

Some strains of *Pseudomonas aeruginosa* (approximately 25%) and *Bacteroides* (approximately 43%) have *in vitro* MIC of <16 mg/l.

Pharmacokinetics

Absorption

Cefotaxime is suitable for intramuscular and intravenous injection however due to poor absorption, it is not suitable for oral administration. After administration of a 1 gram dose, the mean plasma concentration is approximately 20 mg/l (intramuscular, t_{max} = 30 minutes), 102 mg/l (intravenous over 2 to 5 minutes), 27.9 mg/l (30 minute IV infusion).

Single intramuscular injections of 500 mg and 1 g cefotaxime to normal volunteers gave post-dose mean peak plasma levels of 11.7 and 20.5 mg/l at 30 minutes and 1.4 and 3.36 mg/l at 4 hours, respectively. Proportionally higher plasma levels are seen with 2 g doses. Following 8 hourly 500 mg IM injections over 10 days in 15 normal volunteers, pre-dose plasma levels of 0.08 to 0.55 mg/l and 30 minutes post-dose levels of 9.2 to 11.9 mg/l were recorded.

Mean plasma levels (mg/l) obtained following IV bolus injections of cefotaxime 500 mg, 1 g and 2 g administered over 5 minutes to normal volunteers.

Dose	C _{max}	1 hour post-dose	4 hours post-dose
500 mg	38	9.7	1.0
1 g	102	20	1.9
2 g	214	40	3.3

When administered as an infusion over 30 minutes, a 1 g dose gives plasma levels of 27.9, 8.81 and

2.62 mg/l, at 30, 90 and 210 minutes post-dose, respectively. Steady state trough levels of 1.33 mg/l are obtained following 6 hourly 1 g infusions over 14 days. In patients with normal renal function, there is no evidence of cefotaxime accumulation following multiple IV or IM dosing. Following administration via IM, IV bolus and IV infusion, the mean elimination half lives were 1.45, 1.06 and 1.13 hours, respectively.

Distribution

Cefotaxime is 32 to 44% bound to plasma protein with the desacetyl metabolite displaying half of this binding. High renal clearance indicates that cefotaxime has a low binding affinity.

Urinary concentrations vary with route of administration, with 1 g bolus IV, infusion IV and IM injections giving peak levels of 1309, 599 and 903 mg/l, respectively, 4 hours post-dose. Mean peak levels of 35 mg/l are obtained in the bile 30 minutes following a 1 g IV dose, with concentrations reducing to 3.30 mg/l after 4 hours.

Concentrations of cefotaxime in the CSF are considerably lower than plasma. When meninges are inflamed, cefotaxime displays significant diffusion into the cerebrospinal fluid, with concentrations obtained following IV doses of 1 to 2 g being above the MIC for susceptible organisms (i.e. those with MIC <0.5 mg/l).

Biotransformation

Following administration, cefotaxime is rapidly deacetylated in the body, with measurable plasma levels obtained five minutes post-dose. The desacetyl metabolite of cefotaxime is detectable in blood and urine; after administration of a single IV dose of 15 mg/kg to normal volunteers, the mean peak serum levels after 10 minutes for cefotaxime and desacetylcefotaxime were 100 mcg/ml and 5 mcg/ml respectively. Desacetylcefotaxime has a similar antimicrobial spectrum to cefotaxime *in vitro* but is generally less active, ranging from twice as active to 32 times less active, depending on the microbial species. Desacetylcefotaxime undergoes further metabolism to a microbiologically inactive open lactone moiety.

Urinary and faecal recovery accounts for 85 to 90% and 7 to 9.5% of the administered dose respectively, with 70 to 80% recovered in the first 4 hours post-dose. As evidenced in radioactive labelling studies in normal volunteers, 20 to 36% of administered drug is excreted in the urine unchanged, 15 to 25% as the desacetyl metabolite, and 20 to 25% as the opened lactone metabolite.

Elimination

Cefotaxime has a high renal clearance. There is no significant evidence of accumulation after repetitive dosing in subjects with normal renal function. Following IM administration of a 1 g dose the mean plasma clearance is 318 ml/minute/1.73 meters squared. In patients with normal renal function, the elimination half-life of cefotaxime is 0.7 to 1.3 hours, and desacetylcefotaxime approximately 2 hours. Mean elimination half life is 1.45 hour (im), 1.06 hour (rapid iv) and 1.13 hour (30 minute IV infusion).

Special patient groups

In patients with impaired renal function, the terminal half-life of desacetylcefotaxime is prolonged to a greater extent than that of cefotaxime (e.g. in patients with creatinine clearance of 5 to 10 ml/minute, the terminal half-life of cefotaxime is 3.5 hours vs. 13.0 hours for desacetylcefotaxime.)

Interaction studies have demonstrated that orally administered probenecid decreases the renal clearance of cefotaxime by 11 to 32%, and increases cefotaxime retention by 14 to 40%.

The bioavailability and pharmacokinetics of IM administered cefotaxime are not affected by concomitant use of 0.5% lignocaine solution.

Neonatal pharmacokinetics are influenced by birth weight, with elimination half life prolonged at lower birth weights.

Mean pharmacokinetic values following a ten minute infusion of 50 mg/kg to low birth weight neonates.

Mean birth-weight (g)	Peak plasma level (mg/l)	Plasma level 2 hours post-dose (mg/l)	Plasma level 6 hours post-dose (mg/l)	Elimination half-life (h)
1100	115.9	69.8	34.4	4.63
2500	132.7	78.9	38.1	3.37

Indications

Cefotaxime Sandoz is indicated in the treatment of the following infections either before the infecting organism has been identified or when caused by bacteria of established sensitivity: septicaemia; respiratory tract infections - acute and chronic bronchitis, bacterial pneumonia, infected bronchiectasis, lung abscess and post-operative chest infections; urinary tract infections - acute and chronic pyelonephritis, cystitis and asymptomatic bacteriuria; soft tissue infections - cellulitis, peritonitis and wound infections; bone and joint infections - osteomyelitis, septic arthritis; obstetric and gynaecological infections, pelvic inflammatory disease; gonorrhoea - particularly if penicillin-resistant; other bacterial infections - meningitis and other sensitive infections suitable for parenteral antibiotic therapy.

The administration of Cefotaxime Sandoz prophylactically may reduce the incidence of certain post-operative infections in patients undergoing surgical procedures that are classified as contaminated or potentially contaminated or in clean operations where infections would have serious effects. Protection is best ensured by achieving adequate local tissue concentrations at the time contamination is likely to occur. Cefotaxime Sandoz should therefore be administered immediately prior to surgery and if necessary continued in the immediate post-operative period. Administration should usually be stopped within 24 hours since continuing use of any antibiotic in the majority of surgical procedures does not reduce the incidence of subsequent infections.

Dosage and administration

Cefotaxime Sandoz should be administered only by the intramuscular or intravenous routes. The dosage, route of administration and dosage interval will depend on the site and severity of the infection, sensitivity of the pathogens and condition of the patient.

Dosage

Adults

Urinary tract infections

The recommended dose is 2 g daily in two divided doses.

Other infections

For other infections the minimum recommended dosage is 2 g daily in divided doses. This dosage may be increased to 3, 4 or 6 g daily according to the severity of the infection, sensitivity of causative organisms and condition of the patient.

For prevention of post-operative infection

Cefotaxime Sandoz should be administered immediately prior to surgery. A single dose of 1 g is suitable for most procedures. For procedures longer than 4 hours a dose of 2 g is recommended. A single 1 g dose in combination with 500 mg metronidazole is effective in colorectal surgery.

For the treatment of gonorrhoea

Uncomplicated gonorrhoea due to non beta-lactamase producing organisms: One single intramuscular dose of 1 g.

Uncomplicated gonorrhoea due to beta-lactamase producing organisms: One single intramuscular dose of Cefotaxime Sandoz 500 mg plus probenecid, 1 g orally, given 1 hour earlier.

Paediatrics

Neonatal meningitis

The following dosage schedule is recommended:

- 0 to 1 week of age 50 mg/kg IV every 12 hours;
- 1 to 4 weeks of age 50 mg/kg IV every 8 hours.

Children

The usual dosage range is 100 to 150 mg/kg/day in 3 to 4 divided doses. However, in very severe infections doses of up to 200 mg/kg/day may be required.

Impaired renal function

Because of extra-renal elimination, it is only necessary to reduce the dosage of cefotaxime in severe renal failure (creatinine clearance <10 ml/min). After an initial loading dose of 1 g, the daily dose should be halved without change in the frequency of dosing, eg. 1 g every 12 hours becomes 500 mg every 12 hours, 1 g every 8 hours becomes 500 mg every 8 hours, 2 g every 8 hours becomes 1 g every 8 hours.

Elderly

No specific recommendations for the elderly.

Administration

Intravenous and intramuscular injection

Reconstitute Cefotaxime Sandoz 500 mg by adding 2 ml of Water for Injections BP to the vial.

Reconstitute Cefotaxime Sandoz 1 g by adding 4 ml of Water for Injections BP to the vial.

Reconstitute Cefotaxime Sandoz 2 g by adding 10 ml of Water for Injections BP to the vial.

Shake well until dissolved and then withdraw the entire contents of the vial into the syringe and use immediately.

Intravenous infusion

Cefotaxime Sandoz may be administered by intravenous infusion. 1 to 2 g are dissolved in 40 to 100 ml of Water for Injections BP or in the diluents listed in [Pharmaceutical precautions - Instructions for use/handling](#). The prepared infusion should be administered over 20 to 60 minutes.

Contraindications

Known hypersensitivity to cefotaxime or other cephalosporins, or a history of a previous major allergic response to a penicillin due to the possibility of cross sensitivity.

Cefotaxime should not be administered with lignocaine or lidocaine by the intravenous route nor should lignocaine or lidocaine be used as a diluent for: patients with a known history of hypersensitivity to lignocaine or other local anaesthetics of the amide type; patients with non-paced heart block; patients with severe heart failure; infants aged less than 30 months.

Warnings and precautions

Warnings

Hypersensitivity reactions

Cefotaxime Sandoz should not ordinarily be given to those allergic to cephalosporins or to penicillins, especially where an allergic or urticarial reaction has occurred. Patients should be asked about allergies and particularly hypersensitivity to beta-lactam antibiotics. Occurrence of a hypersensitivity reaction requires treatment being stopped. The use of cefotaxime is strictly contraindicated in subjects with a previous history of immediate type hypersensitivity to cephalosporins. In any doubt, it is

essential that a physician be present at the time of the first administration, in order to treat any possible anaphylactic reaction. As there is cross allergy between penicillins and cephalosporins in 5 to 10% of cases, use of the latter should be undertaken with extreme care in penicillin sensitive subjects; careful monitoring is necessary from the first administration. Hypersensitivity reactions (anaphylaxis) occurring with these two antibiotic families may be serious or even fatal.

In the case of anaphylactic shock immediate counter measures are required. Upon first signs of hypersensitivity reactions (e.g. cutaneous reactions, such as skin rashes or urticaria, headache, nausea, restlessness) antibiotic therapy should be discontinued. In cases of severe hypersensitivity reactions or anaphylactic reactions, emergency treatment should be initiated, such as administration of adrenaline or epinephrine and/or glucocorticoids. According to the clinical severity, additional therapeutic measures may be required (e.g. artificial breathing, application of histamine-receptor antagonists). In cases of circulatory collapse, resuscitation must be initiated according to the current guidelines.

Serious bullous reactions

Cases of serious bullous skin reactions like Stevens-Johnson syndrome or toxic epidermal necrolysis have been reported with cefotaxime (see **ADVERSE EFFECTS**). Patients should be advised to contact their doctor immediately prior to continuing treatment if skin and/or mucosal reactions occur.

Pseudomembranous colitis

Diarrhoea, particularly if severe and/or persistent, occurring during treatment or in the initial weeks following treatment with particularly broad spectrum antibiotics, may be symptomatic of *Clostridium difficile*-associated disease. The most severe form of this disease is pseudomembranous colitis, a rare and sometimes fatal condition. Diagnosis of *Clostridium difficile*-associated disease can be made through faecal screening for the pathogen and its cytotoxin. Confirmation of a diagnosis of pseudomembranous colitis should be made by endoscopic and/or histologic examination.

If pseudomembranous colitis is suspected, cefotaxime should be stopped immediately and appropriate specific antibiotic therapy (e.g. oral antibacterial agents effective against *Clostridium difficile*) should be considered. Fluids, electrolytes and protein replacement therapy should be provided as required. *Clostridium difficile*-associated disease can be favoured by faecal stasis. Drugs that delay peristalsis such as opiates and diphenoxylate with atropine may prolong and/or worsen the condition and should not be used during cefotaxime therapy, particularly in bed patients.

Cardiac arrhythmia

Potentially life-threatening arrhythmia has been reported in a very few patients receiving rapid IV cefotaxime administration via a central venous catheter. Cefotaxime given by intermittent IV injection should therefore be administered over a period of 3 to 5 minutes.

Precautions

Cefotaxime should be used with caution in patients with an allergic diathesis such as urticaria or hay fever or with bronchial asthma.

Cefotaxime sodium like other parenteral anti-infective drugs, may be locally irritating to tissues. To minimise the potential for tissue inflammation, infusion sites should be monitored regularly and changed when appropriate. Superinfection with cefotaxime-resistant micro-organisms, including fungi, may occur. In such instances appropriate therapy should be implemented.

Haematological reactions

Leukopenia, neutropenia and, more rarely, agranulocytosis may develop during treatment with cefotaxime, particularly if given over long periods.

Hepatic and renal disease

Transient rises in hepatic enzymes, urea and creatinine have been seen in some patients given cefotaxime, so careful monitoring of hepatic and renal function is advised where any dysfunction exists. For dosage adjustment in moderate and severe renal impairment refer to Dosage and administration.

Severe hepatic insufficiency or reduced hepatic blood flow may inhibit the metabolism of lignocaine or lidocaine causing accumulation and toxicity. In these cases, repeated use of lignocaine or lidocaine should be avoided.

Care should be taken to monitor renal function during treatment with other antibiotics that are potentially nephrotoxic (notably aminoglycosides) or potent diuretics (e.g. furosemide).

Neutropenia

For treatment courses lasting longer than 7 days, the white blood cell count should be monitored and treatment stopped in the event of neutropenia.

Sodium intake

The sodium content of cefotaxime sodium is 48.2 mg per gram and should be taken into account in patients requiring sodium restriction.

Pregnancy and lactation

Use in pregnancy

Assigned Category B1 by the Australian Drug Evaluation Committee. This category includes medicines which have been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation 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.

The safety of cefotaxime when used in pregnancy has not been established. Cefotaxime has not been shown to cause any teratogenic or embryotoxic effects in animals. However, cefotaxime crosses the placenta and it should be administered during known or suspected pregnancy only if in the judgement of the treating clinician such use is deemed essential to the patient's welfare.

Use in lactation

Residual cefotaxime may be present in breast milk at levels corresponding to approximately 0.3% of the maternal dose. Cephalosporins are considered to be compatible with breastfeeding although there are theoretical risks of alterations to infant bowel flora and allergic sensitisation.

Effects on ability to drive and use machines

There are no data to indicate any effect on a person's ability to drive or use machines. This medicine is presumed to be safe or unlikely to produce an effect.

High doses of cefotaxime, particularly in patients with renal insufficiency, may cause encephalopathy (e.g. impairment of consciousness, abnormal movements and convulsions) (see Adverse EFFECTS). Patients should be advised not to drive or operate machinery if any such symptoms occur.

Adverse effects

Hypersensitivity reactions

Fever, and rarely, angioedema, bronchospasm, malaise possibly culminating in anaphylactic shock.

Dermatological

Rash, pruritus, urticaria. Isolated cases of bullous eruptions (erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported.

Gastrointestinal

Nausea, vomiting, abdominal pain, diarrhoea, candidiasis, rarely pseudomembranous colitis (refer to [Warnings and precautions](#)). During treatment with cefotaxime, nausea, vomiting, abdominal pain or diarrhoea may occur. As with all broad spectrum antibiotics diarrhoea may sometimes be a symptom of enterocolitis, which may, in some cases, be accompanied by blood stools. A particular form of enterocolitis that can occur with antibiotics is pseudomembranous colitis, in most cases due to *Clostridium difficile* (refer to [Warnings and precautions](#)).

Hepatobiliary

Moderate regressive increase in transaminases (ALAT, ASAT, LDH, gamma-GT and/or alkaline phosphatase) and/or bilirubin. These laboratory abnormalities, which could also be attributed to the infection, may rarely exceed twice the upper limit of the normal range and elicit a pattern of liver injury, usually cholestatic and most often asymptomatic. Hepatitis (sometimes with jaundice).

Haematological

Leucopenia, granulocytopenia and more rarely agranulocytosis may develop during treatment with cefotaxime. Some cases of eosinophilia and thrombocytopenia, rapidly reversible on treatment withdrawal, have been reported. Rare cases of haemolytic anaemia have also been reported. False positive direct Coombs' tests may occur. It is therefore recommended that the blood count should be monitored if treatment lasts for longer than 7 days.

Renal toxicity

Decrease in renal function, elevation in blood urea and serum creatinine) have been infrequently reported, particularly when co-prescribed with aminoglycosides . Rare cases of interstitial nephritis have been reported in patients treated with cefotaxime.

Neurological

Administration of high doses of beta-lactam antibiotics, including cefotaxime, particularly in patients with renal insufficiency may result in encephalopathy (e.g. impairment of consciousness, abnormal movements and convulsions). Patients should be advised to contact their doctor immediately prior to continuing treatment if such reactions occur.

Cardiovascular

During post-marketing surveillance, potentially life-threatening arrhythmia has been reported in a few patients who received rapid IV administration of cefotaxime through a central venous catheter.

Jarisch-Herxheimer reaction

For the treatment of borreliosis, a Jarisch-Herxheimer reaction may develop during the first days of treatment.

The occurrence of one or more of the following symptoms has been reported after several week's

treatment of borreliosis: skin rash, itching, fever, leucopenia, increase in liver enzymes, difficulty of breathing, joint discomfort.

Other

Fever, shivering, headache, dizziness, joint pain and superinfection.

Superinfection; as with other antibiotics, the use of cefotaxime, especially if prolonged, may result in overgrowth of non-susceptible organisms. Repeated evaluation of the patient's condition is essential. If superinfection occurs during therapy, appropriate measures should be taken.

Pain, phlebitis and tenderness have been reported in approximately 4.8% of cases. Inflammatory reactions at the injection site have also been reported.

As reported with other antibiotics for the treatment of borreliosis, a Jarisch-Herxheimer reaction may develop during the first days of treatment. The occurrence of one or more of the following symptoms has been reported after several week's treatment of borreliosis: skin rash, itching, fever, leucopenia, increase in liver enzymes, difficulty in breathing, joint discomfort. To some extent, these manifestations are consistent with the symptoms of the underlying disease for which the patient is being treated.

Interactions

Medicine interactions

Although cefotaxime and gentamicin have additive microbiological effects they are physically incompatible and should not be combined in a single preparation (e.g. infusion bag).

Orally administered probenecid causes an increase in cefotaxime levels and slightly delays renal clearance.

In common with other cephalosporins, cefotaxime may potentiate the renal toxicity of nephrotoxic drugs.

Cefotaxime may decrease the efficacy of oral contraceptives and additional contraceptive methods should be used.

Cefotaxime should not be combined with bacteriostatic antibiotics (e.g. tetracycline, erythromycin and chloramphenicol) since an antagonistic effect is possible.

Interactions with laboratory tests

Appearance of a false positive Coombs test may occur during treatment with cefotaxime.

In urine glucose testing with non-specific reducing agents, a false positive reaction may occur in patients treated with cefotaxime. This phenomenon does not occur when a glucose-oxidase specific method is used.

Overdosage

Signs and symptoms

No cases of cefotaxime overdosage have been reported. Animal evidence suggests that cefotaxime has a very low toxic potential. LD50 studies in mice and rats administered cefotaxime intravenously have shown no mortality or signs of intoxication up to doses of 716 mg/kg and 2000 mg/kg respectively. In common with all cephalosporins, there is a risk of reversible encephalopathy.

Management

No specific antidote exists. Plasma levels of cefotaxime may be reduced by haemodialysis or peritoneal dialysis.

Pharmaceutical precautions

Instructions for use/handling

If properly stored, undissolved Cefotaxime Sandoz retains its full potency to the date of expiration shown on the pack.

Prior to administration, parenteral medicine products should be inspected visually for particulate matter and discolouration whenever solution and container permit.

The following solutions may be used to reconstitute Cefotaxime Sandoz: Water for Injections BP; 0.9% Sodium Chloride BP; 5% Dextrose Injection BP; 5% Dextrose and 0.9% Sodium Chloride Injection BP; Compound Sodium Lactate Injection BP (Ringers Lactate Injection); 5% Metronidazole solution; Dextran 40 in 0.9% Sodium Chloride solution; Dextran 40 in 5% Dextrose solution; 1% Lignocaine Injection (for intramuscular administration only - refer to [Contraindications](#)).

The reconstituted solution should be used immediately. Cefotaxime Sandoz contains no antimicrobial preservative. It is for single use in one patient only. Discard any residue.

Incompatibilities

Cefotaxime is incompatible with aqueous solutions of sodium bicarbonate and infusion solutions with a pH greater than 7.

Cefotaxime is physically incompatible with aminoglycosides. Where combination therapy is required, the drugs should be administered separately and not mixed together as a single preparation.

Special precautions for storage

Store at or below 25°C. This medicine should not be used after the expiry date shown on the pack.

Medicine classification

Prescription Medicine.

Package quantities

Single vial packs.

Further information

Displacement volumes

500 mg vial

Cefotaxime Sandoz injection 500 mg is packaged in a 15 ml vial. Reconstitution with 2 ml diluent results in a final volume of approximately 2.3 ml.

1 g vial

Cefotaxime Sandoz injection 1 g is packaged in a 20 ml vial. Reconstitution with 4 ml diluent results in

a final volume of approximately 4.8 ml.

2 g vial

Cefotaxime Sandoz injection 2 g is packaged in a 20 ml or 50 ml vial. Reconstitution with 10 ml diluent results in a final volume of approximately 11.5 ml. Reconstitution with 40 ml diluent results in a final volume of approximately 40.5 ml. Reconstitution with 50 ml diluent results in a final volume of approximately 50.5 ml. Reconstitution with 100 ml diluent results in a final volume of approximately 100.5 ml.

List of excipients

Nil.

Name and address

Novartis New Zealand Limited
Private Bag 65904 Mairangi Bay
AUCKLAND 0754

Telephone: (09) 361 8100

Date of preparation

January 2012