

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINE

ROXICEF® 750mg, powder for solution for injection or infusion (IM, IV)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial of Roxicef ®750mg contains Cefuroxime Sodium equivalent to Cefuroxime 750mg.

The total quantity of Sodium per vial is as follows:

Roxicef Strength	Amount of Sodium per vial
750 mg	42 mg

For a full list of excipients, (see section 6.1)

3. PHARMACEUTICAL FORM

Powder for solution for injection or infusion (IM, IV).

White or almost white powder in a 10ml vial (glass type III) sealed with purple colour flip off seals.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Roxicef is indicated for the treatment of the infections listed below in adults and children, including neonates (from birth) (see sections 4.4 and 5.1).

- Community acquired pneumonia
- Acute exacerbations of chronic bronchitis
- Complicated urinary tract infections, including pyelonephritis
- Soft-tissue infections: cellulitis, erysipelas and wound infections
- Intraabdominal infections (see section 4.4)
- Prophylaxis against infection in gastrointestinal (including oesophageal), orthopaedic, cardiovascular, and gynaecological surgery (including caesarean section).

In the treatment and prevention of infections in which it is very likely that anaerobic organisms will be encountered, Cefuroxime should be administered with additional appropriate antibacterial agents.

Consideration should be given to official guidance on the appropriate use of antibacterial agents.

4.2 Posology and method of administration

Posology

Table 1. Adults and children ≥ 40 kg

Indication	Dosage
Community acquired pneumonia and acute exacerbations of chronic bronchitis	750 mg every 8 hours (intravenously or intramuscularly)
Soft-tissue infections: cellulitis, erysipelas and wound infections.	
Intra-abdominal infections	
Complicated urinary tract infections, including pyelonephritis	1.5 g every 8 hours (intravenously or intramuscularly)
Severe infections	750 mg every 6 hours (intravenously) 1.5 g every 8 hours (intravenously)
Surgical prophylaxis for gastrointestinal, gynaecological surgery (including caesarean section) and orthopaedic operations	1.5 g with the induction of anaesthesia. This may be supplemented with two 750 mg doses (intramuscularly) after 8 hours and 16 hours
Surgical prophylaxis for cardiovascular and oesophageal	1.5 g with induction of anaesthesia followed by 750 mg (intramuscularly) every 8 hours for a further 24 hours

Table 2. Children < 40 kg

	Infants and toddlers > 3 weeks and children < 40 kg	Infants (birth to 3 weeks)
Community acquired pneumonia	30 to 100 mg/kg/day (intravenously) given as 3 or 4 divided doses; a dose of 60 mg/kg/day is appropriate for most infections	30 to 100 mg/kg/day (intravenously) given as 2 or 3 divided doses (see section 5.2)
Complicated urinary tract infections, including pyelonephritis		
Soft-tissue infections: cellulitis, erysipelas and wound infections		
Intra-abdominal infections		

Renal impairment

Cefuroxime is primarily excreted by the kidneys. Therefore, as with all such antibiotics, in patients with markedly impaired renal function it is recommended that the dosage of Roxicef should be reduced to compensate for its slower excretion.

Table 3. Recommended doses for Roxicef in renal impairment

Creatinine clearance	T _{1/2} (hrs)	Dose (mg)
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> 20 mL/min/1.73 m ²	1.7–2.6	It is not necessary to reduce the standard dose (750 mg to 1.5 g three times daily).
10–20 mL/min/1.73 m ²	4.3–6.5	750 mg twice daily
< 10 mL/min/1.73 m ²	14.8–22.3	750 mg once daily
Patients on haemodialysis	3.75	A further 750 mg dose should be given intravenously or intramuscularly at the end of each dialysis; in addition to parenteral use, cefuroxime sodium can be incorporated into the peritoneal dialysis fluid (usually 250 mg for every 2 litres of dialysis fluid).
Patients in renal failure on continuous arteriovenous haemodialysis (CAVH) or high-flux haemo-filtration (HF) in intensive therapy units	7.9–12.6 (CAVH) 1.6 (HF)	750 mg twice daily; for low-flux haemo-filtration follow the dosage recommended under impaired renal function.

Hepatic impairment

Cefuroxime is primarily eliminated by the kidney. In patients with hepatic dysfunction this is not expected to affect the pharmacokinetics of Cefuroxime.

Method of administration

Roxicef should be administered by intravenous injection over a period of 3 to 5 minutes directly into a vein or via a drip tube or infusion over 30 to 60 minutes, or by deep intramuscular injection.

Intramuscular injections should be injected well within the bulk of a relatively large muscle and not more than 750 mg should be injected at one site. For doses greater than 1.5 g intravenous administration should be used. For instructions on reconstitution of the medicinal product before administration, see section 6.6.

750 mg, 1.5 g powder for solution for infusion (Monovial presentation).

For instructions on preparation of the medicinal product before administration, see section 6.6.

4.3 Contraindications

Hypersensitivity to Cefuroxime or to any of the excipients listed in section 6.1.

Patients with known hypersensitivity to Cephalosporin antibiotics.

History of severe hypersensitivity (e.g. anaphylactic reaction) to any other type of Betalactam antibacterial agent (Penicillins, Monobactams and Carbapenems).

4.4 Special warnings and precautions for use

Hypersensitivity reactions

As with all beta-lactam antibacterial agents, serious and occasionally fatal hypersensitivity reactions have been reported. In case of severe hypersensitivity reactions, treatment with Cefuroxime must be discontinued immediately and adequate emergency measures must be initiated.

Before beginning treatment, it should be established whether the patient has a history of severe hypersensitivity reactions to Cefuroxime, to other Cephalosporins or to any other type of beta-lactam agent. Caution should be used if Cefuroxime is given to patients with a history of non-severe hypersensitivity to other beta-lactam agents.

Concurrent treatment with potent diuretics or aminoglycosides

Cephalosporin antibiotics at high dosage should be given with caution to patients receiving concurrent treatment with potent diuretics such as furosemide or aminoglycosides. Renal impairment has been reported during use of these combinations. Renal function should be monitored in the elderly and those with known pre-existing renal impairment (see section 4.2).

Overgrowth of non-susceptible microorganisms

Use of Cefuroxime may result in the overgrowth of *Candida*. Prolonged use may also result in the overgrowth of other non-susceptible micro-organisms (e.g. enterococci and *Clostridium difficile*), which may require interruption of treatment (see section 4.8).

Antibacterial agent-associated pseudomembranous colitis has been reported with use of Cefuroxime and may range in severity from mild to life threatening. This diagnosis should be considered in patients with diarrhoea during or subsequent to the administration of Cefuroxime (see section 4.8). Discontinuation of therapy with Cefuroxime and the administration of specific treatment for *Clostridium difficile* should be considered. Medicinal products that inhibit peristalsis should not be given.

Intra-abdominal infections

Due to its spectrum of activity, Cefuroxime is not suitable for the treatment of infections caused by Gram-negative non-fermenting bacteria (see section 5.1).

Interference with diagnostic tests

The development of a positive Coomb's Test associated with the use of Cefuroxime may interfere with cross matching of blood (see section 4.8).

Slight interference with Copper reduction methods (Benedict's, Fehling's, Clinitest) may be observed. However, this should not lead to false-positive results, as may be experienced with some other Cephalosporins.

As a false negative result may occur in the ferricyanide test, it is recommended that either the glucose oxidase or hexokinase methods are used to determine blood/plasma glucose levels in patients receiving Cefuroxime Sodium.

Important information about excipients

Roxicef powder for solution for injection and infusion contains sodium. This should be considered for patients who are on a controlled sodium diet.

Each 750 mg vial contains 42 mg sodium.

4.5 Interactions with other medicinal products and other forms of interaction

Cefuroxime may affect the gut flora, leading to lower oestrogen reabsorption and reduced efficacy of combined oral contraceptives.

Cefuroxime is excreted by glomerular filtration and tubular secretion. Concomitant use of probenecid is not recommended. Concurrent administration of Probenecid prolongs the excretion of the antibiotic and produces an elevated peak serum level.

Potential nephrotoxic drugs and loop diuretics

High-dosage treatments with Cephalosporins should be carried out with caution on patients who are taking strongacting diuretics (such as Furosemide) or potential nephrotoxic preparations (such as Aminoglycoside antibiotics), since impairment of renal function through such combinations cannot be ruled out.

Other Interactions

Determination of blood/plasma glucose levels: refer to section 4.4. Concomitant use with oral anticoagulants may give rise to increased international normalised ratio (INR).

4.6 Pregnancy and Lactation

Pregnancy

There are limited amounts of data from the use of Cefuroxime in pregnant women. Studies in animals have shown no reproductive toxicity (see section 5.3). Roxicef should be prescribed to pregnant women only if the benefit outweighs the risk.

Cefuroxime has been shown to cross the placenta and attain therapeutic levels in amniotic fluid and cord blood after intramuscular or intravenous dose to the mother.

Breastfeeding

Cefuroxime is excreted in human milk in small quantities. Adverse reactions at therapeutic doses are not expected, although a risk of diarrhoea and fungus infection of the mucous membranes cannot be excluded. A decision must be made whether to discontinue breastfeeding or to discontinue/abstain from Cefuroxime therapy taking into account the benefit of breast feeding for the child and the benefit of therapy for the woman.

Fertility

There are no data on the effects of Cefuroxime Sodium on fertility in humans. Reproductive studies in animals have shown no effects on fertility.

4.7 Effects on ability to drive and use machines

No studies on the effects of Cefuroxime on the ability to drive and use machines have been performed. However, based on known adverse reactions, Cefuroxime is unlikely to have an effect on the ability to drive and use machines.

4.8 Undesirable effects

The most common adverse reactions are neutropenia, eosinophilia, transient rise in liver enzymes or bilirubin, particularly in patients with pre-existing liver disease, but there is no evidence of harm to the liver and injection site reactions.

The frequency categories assigned to the adverse reactions below are estimates, as for most reactions suitable data for calculating incidence are not available. In addition the incidence of adverse reactions associated with Cefuroxime Sodium may vary according to the indication.

Data from clinical trials were used to determine the frequency of very common to rare adverse reactions. The frequencies assigned to all other adverse reactions (i.e. those occurring at <1/10,000) were mainly determined using post-marketing data, and refer to a reporting rate rather than a true frequency.

Treatment related adverse reactions, all grades, are listed below by MedDRA body system organ class, frequency and grade of severity. The following convention has been utilised for the classification of frequency:

very common $\geq 1/10$;

common $\geq 1/100$ to $< 1/10$;

uncommon $\geq 1/1,000$ to $< 1/100$;

rare $\geq 1/10,000$ to $< 1/1,000$;

very rare $< 1/10,000$

and not known (cannot be estimated from the available data).

System organ class	Common	Uncommon	Not known
<u>Infections and infestations</u>			<i>Candida</i> overgrowth, overgrowth of <i>Clostridium difficile</i>
<u>Blood and lymphatic system disorders</u>	neutropenia, eosinophilia, decreased haemoglobin concentration	leukopenia, positive Coomb's test	thrombocytopenia, haemolytic anaemia
<u>Immune system disorders</u>			drug fever, interstitial nephritis, anaphylaxis, cutaneous vasculitis
<u>Gastrointestinal disorders</u>		gastrointestinal disturbance	pseudomembranous colitis (see section 4.4)
<u>Hepatobiliary disorders</u>	transient rise in liver enzymes	transient rise in bilirubin	
<u>Skin and subcutaneous tissue disorders</u>		skin rash, urticaria and pruritus	erythema multiforme, toxic epidermal necrolysis and

			StevensJohnson syndrome, angioneurotic oedema
<u>Renal and urinary disorders</u>			elevations in serum creatinine, elevations in blood urea nitrogen and decreased creatinine clearance (see section 4.4)
<u>General disorders and administration site conditions</u>	injection site reactions which may include pain and thrombophlebitis		
<p><i>Description of selected adverse reactions</i></p> <p>Cephalosporins as a class tend to be absorbed onto the surface of red cell membranes and react with antibodies directed against the drug to produce a positive Coomb's test (which can interfere with cross matching of blood) and very rarely haemolytic anaemia.</p> <p>Transient rises in serum liver enzymes or bilirubin have been observed which are usually reversible.</p> <p>Pain at the intramuscular injection site is more likely at higher doses. However it is unlikely to be a cause for discontinuation of treatment.</p>			

Paediatric population

The safety profile for Cefuroxime Sodium in children is consistent with the profile in adults.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions.

4.9 Overdose

Overdose can lead to neurological sequelae including encephalopathy, convulsions and coma. Symptoms of overdose can occur if the dose is not reduced appropriately in patients with renal impairment (see sections 4.2 and 4.4).

Serum levels of Cefuroxime can be reduced by haemodialysis or peritoneal dialysis.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: antibacterials for systemic use, second-generation Cephalosporins, ATC code: J01DC02

Mechanism of action

Cefuroxime inhibits bacterial cell wall synthesis following attachment to penicillin binding proteins (PBPs). This results in the interruption of cell wall (peptidoglycan) biosynthesis, which leads to bacterial cell lysis and death.

Mechanism of resistance

Bacterial resistance to Cefuroxime may be due to one or more of the following mechanisms:

- hydrolysis by betalactamases including (but not limited to) extended-spectrum Betalactamases (ESBLs), and AmpC enzymes, that may be induced or stably derepressed in certain aerobic Gram-negative bacterial species;
- reduced affinity of penicillinbinding proteins for Cefuroxime;
- outer membrane impermeability, which restricts access of Cefuroxime to penicillin binding proteins in Gramnegative bacteria;
- bacterial efflux pumps.

Organisms that have acquired resistance to other injectable Cephalosporins are expected to be resistant to Cefuroxime.

Depending on the mechanism of resistance, organisms with acquired resistance to Penicillins may demonstrate reduced susceptibility or resistance to Cefuroxime.

Cefuroxime Sodium breakpoints

Minimum inhibitory concentration (MIC) breakpoints established by the European Committee on Antimicrobial Susceptibility Testing (EUCAST) are as follows:

Microorganism	Breakpoints (mg/L)	
	Susceptible	Resistant
Enterobacteriaceae ¹	≤8 ²	>8
Staphylococcus spp.	Note ³	Note ³
Streptococcus A, B, C and G	Note ⁴	Note ⁴
Streptococcus pneumoniae	≤0.5	>1
Streptococcus (other)	≤0.5	>0.5
Haemophilus influenzae	≤1	>2
Moraxella catarrhalis	≤4	>8
Nonspecies related breakpoints ¹	≤4 ⁵	>8 ⁵

1 The Cephalosporin breakpoints for Enterobacteriaceae will detect all clinically important resistance mechanisms (including ESBL and plasmid mediated AmpC). Some strains that produce betalactamases are susceptible or intermediate to 3rd or 4th generation Cephalosporins with these breakpoints and should be reported as found, i.e. the presence or absence of an ESBL does not in itself influence the categorization of susceptibility. In many areas, ESBL detection and characterization is recommended or mandatory for infection control purposes.

2 Breakpoint relates to a dosage of 1.5 g × 3 and to E. coli, P. mirabilis and Klebsiella spp. Only

3 Susceptibility of staphylococci to Cephalosporins is inferred from the methicillin susceptibility except for ceftazidime and cefixime and ceftibuten, which do not have breakpoints and should not be used for staphylococcal infections.

4 The susceptibility of streptococcus groups A, B, C and G to Cephalosporins is inferred from the benzylpenicillin susceptibility.

5 Breakpoints apply to daily intravenous dose of 750 mg × 3 and a high dose of at least 1.5 g × 3.

Microbiological susceptibility

The prevalence of acquired resistance may vary geographically and with time for selected species and local information on resistance is desirable, particularly when treating severe infections. As necessary, expert advice should be sought when the local prevalence of resistance is known and the utility of the agent in at least some types of infections is questionable.

Cefuroxime is usually active against the following microorganisms *in vitro*.

Commonly susceptible species

Gram-positive aerobes:

Staphylococcus aureus (methicillin-susceptible)

Streptococcus pyogenes

Streptococcus agalactiae

Gram-negative aerobes:

Haemophilus parainfluenzae

Moraxella catarrhalis

Microorganisms for which acquired resistance may be a problem

Gram-positive aerobes:

Streptococcus pneumoniae

Streptococcus mitis (viridans group)

Gram-negative aerobes:

Citrobacter spp. not including *C. freundii*

Enterobacter spp. not including *E. aerogenes* and *E. cloacae*

Escherichia coli

Haemophilus influenzae

Klebsiella pneumoniae

Proteus mirabilis

Proteus spp. not including *P. penneri* and *P. vulgaris*

Providencia spp.

Salmonella spp.

Gram-positive anaerobes:

Peptostreptococcus spp.

Propionibacterium spp.

Gram-negative anaerobes:

Fusobacterium spp.

Bacteroides spp.

Inherently resistant microorganisms

Gram-positive aerobes:

Enterococcus faecalis

Enterococcus faecium

Gram-negative aerobes:

Acinetobacter spp.

Burkholderia cepacia

Campylobacter spp.

Citrobacter freundii

Enterobacter aerogenes

Enterobacter cloacae

Morganella morganii

Proteus penneri

Proteus vulgaris

Pseudomonas aeruginosa

Serratia marcescens

Stenotrophomonas maltophilia

Gram-positive anaerobes:

Clostridium difficile

Gram-negative anaerobes:

Bacteroides fragilis

Others:

Chlamydia spp.

Mycoplasma spp.

Legionella spp.

\$ All methicillin-resistant *S. aureus* are resistant to Cefuroxime

In vitro the activities of Cefuroxime Sodium and Aminoglycoside antibiotics in combination have been shown to be at least additive with occasional evidence of synergy.

5.2 Pharmacokinetic properties

Absorption

After intramuscular (IM) injection of Cefuroxime to normal volunteers, the mean peak serum concentrations ranged from 27 to 35 µg/mL for a 750 mg dose and from 33 to 40 µg/mL for a 1000 mg dose, and were achieved within 30 to 60 minutes after administration. Following intravenous (IV) doses of 750 and 1500 mg, serum concentrations were approximately 50 and 100 µg/mL, respectively, at 15 minutes.

AUC and C_{max} appear to increase linearly with increase in dose over the single dose range of 250 to 1000 mg following IM and IV administration. There was no evidence of accumulation

of Cefuroxime in the serum from normal volunteers following repeat intravenous administration of 1500 mg doses every 8 hours.

Distribution

Protein binding has been stated as 33 to 50%, depending on the methodology used. The average volume of distribution ranges from 9.3 to 15.8 L/1.73 m² following IM or IV administration over the dosage range of 250 to 1000 mg.

Concentrations of Cefuroxime in excess of the minimum inhibitory levels for common pathogens can be achieved in the tonsilla, sinus tissues, bronchial mucosa, bone, pleural fluid, joint fluid, synovial fluid, interstitial fluid, bile, sputum and aqueous humour. Cefuroxime passes the blood-brain barrier when the meninges are inflamed.

Biotransformation

Cefuroxime is not metabolised.

Elimination

Cefuroxime is excreted by glomerular filtration and tubular secretion. The serum half-life after either intramuscular or intravenous injection is approximately 70 minutes. There is an almost complete recovery (85 to 90%) of unchanged cefuroxime in urine within 24 hours of administration. The majority of the Cefuroxime is excreted within the first 6 hours.

The average renal clearance ranges from 114 to 170 mL/min/1.73 m² following IM or IV administration over the dosage range of 250 to 1000 mg.

Special patient populations

Gender

No differences in the pharmacokinetics of Cefuroxime were observed between males and females following a single IV bolus injection of 1000 mg of Cefuroxime as the Sodium salt.

Elderly

Following IM or IV administration, the absorption, distribution and excretion of Cefuroxime in elderly patients are similar to younger patients with equivalent renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in Cefuroxime dose selection, and it may be useful to monitor renal function (see section 4.2).

Paediatrics

The serum half-life of Cefuroxime has been shown to be substantially prolonged in neonates according to gestational age. However, in older infants (aged >3 weeks) and in children, the serum half-life of 60 to 90 minutes is similar to that observed in adults.

Renal impairment

Cefuroxime is primarily excreted by the kidneys. As with all such antibiotics, in patients with markedly impaired renal function (i.e. $Cl_{cr} < 20$ mL/minute) it is recommended that the dosage of Cefuroxime should be reduced to compensate for its slower excretion (see section 4.2). Cefuroxime is effectively removed by haemodialysis and peritoneal dialysis.

Hepatic impairment

Since Cefuroxime is primarily eliminated by the kidney, hepatic dysfunction is not expected to have an effect on the pharmacokinetics of Cefuroxime.

PK/PD relationship

For cephalosporins, the most important pharmacokinetic-pharmacodynamic index correlating with *in vivo* efficacy has been shown to be the percentage of the dosing interval (%T) that the unbound concentration remains above the minimum inhibitory concentration (MIC) of Cefuroxime for individual target species (i.e. %T>MIC).

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity and toxicity to reproduction and development. No carcinogenicity studies have been performed; however, there is no evidence to suggest carcinogenic potential.

Gamma glutamyl transpeptidase activity in rat urine is inhibited by various Cephalosporins; however, the level of inhibition is less with Cefuroxime. This may have significance in the interference in clinical laboratory tests in humans.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Roxicef powder for solution for injection and infusion contains sodium.

This should be considered for patients who are on a controlled sodium diet. Each 750 mg vial contains 42 mg sodium.

6.2 Incompatibilities

Cefuroxime is compatible with most commonly used intravenous fluids and electrolyte solutions.

The pH of 2.74% w/v Sodium Bicarbonate injection BP considerably affects the colour of solutions and therefore this solution is not recommended for the dilution of Roxicef. However, if required, for patients receiving Sodium Bicarbonate injection by infusion the Roxicef may be introduced into the tube of the giving set.

Roxicef should not be mixed in the syringe with aminoglycoside antibiotics.

6.3 Shelf life

3 years / 36 months.

Do not use this medicine after the expiry date shown on the pack after EXP. The expiry date refers to the last day of that month.

6.4 Special precautions for storage

Store below 30°C. **6.5 Nature and contents of the outer packaging**

Primary Packaging:

White or almost white powder in a 10ml vial (glass type III) sealed with purple colour flip off seals. 1 or 10 vial(s) per box.

Secondary Packaging:

Place one/ten vial(s) in a carton along with a Patient Information Leaflet

Not all pack size may be marketed in your country.

6.6 Special precautions for disposal and handling

Instructions for constitution

Table 4. Additional volumes and concentrations which may be useful when fractional doses are required.

Additional volumes and concentrations, which may be useful when fractional doses are required				
Vial size	Routes of administration	Physical State	Amount of water to be added (ml)	Approximate Cefuroxime concentration (mg/ml)**
750 mg powder for solution for injection or infusion				
750 mg	intramuscular	suspension	3 ml	216
	intravenous bolus	solution	at least 6 ml	116
	intravenous infusion	solution	at least 6 ml	116

** The resulting volume of the solution of Cefuroxime in reconstitution medium is increased due the displacement factor of the drug substance resulting in the listed concentrations in mg/mL.

Roxicef 750 mg powder for solution for infusion (Monovial presentation)

Preparation of solution for intravenous infusion

The contents of the Monovial are added to small volume infusion bags containing 0.9% w/v Sodium Chloride Injection BP, or 5% Dextrose Injection, or another compatible fluid.

1. Peel off the removable top part of the label and remove the cap.

2. Insert the needle of the Monovial into the additive port of the infusion bag.
3. To activate, push the plastic needle holder of the Monovial down onto the vial shoulder until a "click" is heard.
4. Holding it upright, fill the vial to approximately two-thirds capacity by squeezing the bag several times.
5. Shake the vial to reconstitute the Cefuroxime Sodium.
6. With the vial uppermost, transfer the reconstituted Cefuroxime Sodium into the infusion bag by squeezing and releasing the bag.
7. Repeat steps 4 to 6 to rinse the inside of the vial. Dispose of the empty Monovial safely. Check that the powder has dissolved, and that the bag has no leaks.

Compatibility

1.5 g Cefuroxime Sodium constituted with 15 mL Water for Injection may be added to metronidazole injection (500 mg/100 mL) and both retain their activity for up to 24 hours below 25°C.

1.5 g Cefuroxime Sodium is compatible with azlocillin 1 g (in 15 mL) or 5 g (in 50 mL) for up to 24 hours at 4°C or 6 hours below 25°C.

Cefuroxime Sodium (5 mg/mL) in 5% w/v or 10% w/v xylitol injection may be stored for up to 24 hours at 25°C.

Cefuroxime Sodium is compatible with aqueous solutions containing up to 1% lidocaine hydrochloride.

Cefuroxime Sodium is compatible with the following infusion fluids. It will retain potency for up to 24 hours at room temperature in:

0.9% w/v Sodium Chloride Injection BP
5% Dextrose Injection BP
0.18% w/v Sodium Chloride plus 4% Dextrose Injection BP
5% Dextrose and 0.9% w/v Sodium Chloride Injection BP
5% Dextrose and 0.45% Sodium Chloride Injection
5% Dextrose and 0.225% Sodium Chloride Injection
10% Dextrose Injection
10% Invert Sugar in Water for Injection
Ringer's Injection USP
Lactated Ringer's Injection USP
M/6 Sodium Lactate Injection
Compound Sodium Lactate Injection BP (Hartmann's Solution).

The stability of Cefuroxime Sodium in 0.9% w/v Sodium Chloride Injection BP and in 5% Dextrose Injection is not affected by the presence of Hydrocortisone Sodium phosphate.

Cefuroxime Sodium has also been found compatible for 24 hours at room temperature when admixed in IV infusion with:

Heparin (10 and 50 units/mL) in 0.9% w/v Sodium Chloride Injection BP; Potassium Chloride (10 and 40 mEqL) in 0.9% w/v Sodium Chloride Injection BP.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. NAME AND ADDRESS OF MANUFACTURER

Medreich Limited

Plot No. 45 A & B,
Anrich Industrial Estate, I. D.A Bollaram,
Medak District - 502 325
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For: SANOFI



8. CONDITIONS FOR PRESCRIPTION AND RELEASE

List I

Sale with medical prescription

Sale without medical prescription

9. DATE OF REVISION OF THE TEXT

July 2015

NAFDAQ REG. No.: 04-6536