Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Cefuroxime 1.5 g Powder for Injection/Infusion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial contains 1.5g cefuroxime (as sodium salt).

Excipients with known effects:
Each vial contains 81.3 mg sodium.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for solution for injection or infusion/ Powder for suspension for injection

Vials containing a white or almost white powder

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Cefuroxime 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.
- Intra-abdominal 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

Table1.Adultsandchildren≥40kg

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 operations	1.5 g with induction of anaesthesia followed by 750 mg (intramuscularly) every 8 hours for a further 24 hours.

Paediatricpopulation

Table2.Children<40kg

	Infantsandtoddlers>3 weeks and children < 40 kg	**Infants(birthto3weeks)**
Community acquired		30 to 100 mg/kg/day (intravenously) given as 2 or 3 divided doses (see section 5.2)
pneumonia		
Complicated urinary tract	30 to 100 mg/kg/day	
infections, including	(intravenously) given as 3 or	
pyelonephritis	4 divided doses; a dose of 60	
Soft-tissue infections:	mg/kg/day is appropriate for	
cellulitis, erysipelas and	most infections	
wound infections.		
Intra-abdominal infections		

Renalimpairment
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 cefuroxime should be reduced to compensate for its slower excretion.

Table3.Recommendeddosesforcefuroximeinrenalimpairment

Creatinineclearance	**T1/2(hrs)**	**Dosemg**
> 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 haemofiltration (HF) in intensive therapy units	7.9-12.6 (CAVH) 1.6 (HF)	750 mg twice daily; for low flux haemofiltration follow the dosage recommended under impaired renal function.

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

Methodofadministration
Cefuroxime should be administered by intravenous injection over a period of 3 to 5 minutes directly into a vein or via a drip tube 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.

4.3 Contraindications

Hypersensitivity to the active substance or 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 beta-lactam antibacterial agent (penicillins, monobactams and carbapenems).

4.4 Special warnings and precautions for use

Hypersensitivityreactions

As with all beta-lactam antibacterial agents, serious and occasionally fatal hypersensitivity reactions have been reported. There have been reports of hypersensitivity reactions which progressed to Kounis syndrome (acute allergic coronary arteriospasm that can result in myocardial infarction, see section 4.8). 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.

Severe cutaneous adverse reactions (SCARS)

Severe cutaneous adverse reactions including: Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and drug reaction with eosinophilia and systemic symptoms (DRESS), which can be life-threatening or fatal, have been reported in association with cefuroxime treatment (see section 4.8).
At the time of prescription patients should be advised of the signs and symptoms and monitored closely for skin reactions. If signs and symptoms suggestive of these reactions appear, cefuroxime should be withdrawn immediately and an alternative treatment considered. If the patient has developed a serious reaction such as SJS, TEN or DRESS with the use of cefuroxime, treatment with cefuroxime must not be restarted in this patient at any time.

Concurrenttreatmentwithpotentdiureticsoraminoglycosides

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).

Overgrowthofnon-susceptiblemicroorganisms
Use of cefuroxime may result in the overgrowth of *Candida*. Prolonged use may also result in the overgrowth of other non-susceptible microorganisms (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.

Intracameraluseandeyedisorders
Cefuroxime is not formulated for intracameral use. Individual cases and clusters of serious ocular adverse reactions have been reported following unapproved intracameral use of cefuroxime sodium compounded from vials approved for intravenous/intramuscular administration. These reactions included macular oedema, retinal oedema, retinal detachment, retinal toxicity, visual impairment, visual acuity reduced, vision blurred, corneal opacity and corneal oedema.

Intra-abdominalinfections

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).

Interferencewithdiagnostictests

The development of a positive Coombs 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.

Neurotoxicity
Reports of neurotoxicity have been identified in association with cephalosporin treatment. Symptoms may include encephalopathy, myoclonus and seizures. Elderly patients, patients with severe renal impairment or central nervous system disorders are particularly at risk. If cefuroxime sodium associated neurotoxicity is suspected, discontinuation of cefuroxime sodium should be considered (see Section 4.8).

Importantinformationaboutexcipients
This medicinal product contains 81.3 mg sodium per vial, equivalent to 4% of the WHO recommended maximum daily intake of 2 g sodium for an adult. To be taken into consideration by patients on a controlled sodium diet.

4.5 Interaction 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 strong-acting 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: Please refer to section 4.4.
Concomitant use with oral anticoagulants may give rise to increased international normalised ratio (INR).

4.6 Fertility, 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). Cefuroxime 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 breast-feeding 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 ≥ 1/10; common ≥ 1/100 to < 1/10; uncommon ≥ 1/1 000 to < 1/100; rare ≥ 1/10 000 to < 1/1 000; very rare < 1/10 000 and not known (cannot be estimated from the available data).

Systemorgan class	**Common**	**Uncommon**	**Notknown**
Infectionsandinfestations			*Candida* overgrowth, overgrowth of *Clostridium difficile*
Blood andlymphaticsystem disorders	neutropenia, eosinophilia, decreased haemoglobin concentration	leukopenia, positive Coombs test	thrombocytopenia, haemolytic anaemia
Immunesystemdisorders			drug fever, interstitial nephritis, anaphylaxis, cutaneous vasculitis
Cardiac disorders			Kounis syndrome
Gastrointestinal disorders		gastrointestinal disturbance	pseudomembranous colitis (see section 4.4)
Hepatobiliarydisorders	transient rise in liver enzymes	transient rise in bilirubin	
Skin andsubcutaneoustissuedisorders		skin rash, urticaria and pruritus	erythema multiforme, toxic epidermal necrolysis and Stevens-Johnson syndrome, angioneurotic oedema, Drug reaction with Eosinophilia and Systemic Symptoms (DRESS)
Renalandurinarydisorders			elevations in serum creatinine, elevations in blood urea nitrogen and decreased creatinine clearance (see section 4.4)
General disordersandadministrationsite conditions	injection site reactions which may include pain and thrombophlebitis		
Descriptionofselectedadversereactions 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. Transient rises in serum liver enzymes or bilirubin have been observed which are usually reversible. Pain at the intramuscular injection site is more likely at higher doses. However it is unlikely to be a cause for discontinuation of treatment. There have been reports of neurological adverse reactions including encephalopathy, tremor, myoclonia and convulsions associated with the use of cephalosporins. Most cases occurred in patients with severe renal impairment (see Section 4.4).			

Paediatricpopulation
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 via:

HPRA Pharmacovigilance
Website: www.hpra.ie

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

MechanismofAction:

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.

Mechanismsofresistance

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

- Hydrolysis by beta-lactamases including (but not limited to) extended-spectrum beta- lactamases (ESBLs), and Amp-C enzymes, that may be induced or stably de- repressed in certain aerobic Gram-negative bacterial species;
- Reduced affinity of penicillin-binding proteins for cefuroxime;
- Outer membrane impermeability, which restricts access of cefuroxime to penicillin binding proteins in Gram-negative 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.

Susceptibility testingbreakpoints

MIC (minimum inhibitory concentration) interpretive criteria for susceptibility testing have been established by the European Committee on Antimicrobial Susceptibility Testing (EUCAST) for cefuroxime intravenous (IV) and are listed here: https://www.ema.europa.eu/documents/other/minimum-inhibitory-concentration-mic-breakpoints_en.xlsx

Microbiologicalsusceptibility

The prevalence of acquired resistance may vary geographically and with time for selected species and local information on resistance is therefore 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 *invitro*.

Commonlysusceptiblespecies
Gram-positiveaerobes: *Staphylococcusaureus(methicillin-susceptible)** *Streptococcus pyogenes Streptococcusagalactiae*
Gram-negative aerobes:*Haemophilusparainfluenzae Moraxella catarrhalis*
Microorganismsforwhichacquiredresistancemaybea problem
Gram-positive aerobes:*Streptococcus pneumoniae Streptococcusmitis*(viridans group)
Gram-negativeaerobes: *Citrobacter*spp. not including *C. freundii* *Enterobacter*spp. not including *E.aerogenes*and *E.cloacae Escherichia coli* *Haemophilusinfluenzae Klebsiella pneumoniae* *Proteus mirabilis* *Proteus spp. (other than P. penneri and P. vulgaris)* *Providencia spp.* *Salmonella spp.*
Gram-positiveanaerobes: *Peptostreptococcus*spp. *Propionibacterium*spp.
Gram-negativeanaerobes: *Fusobacterium*spp.

*Bacteroides*spp.
Inherentlyresistantmicroorganisms
Gram-positiveaerobes: *Enterococcusfaecalis* *Enterococcusfaecium*
Gram-negativeaerobes: *Acinetobacter* spp. *Burkholderia cepacia Campylobacter* spp. *Citerobacter freundii Enterobacteraerogenes Enterobacter cloacae Morganella morganii Proteus penneriProteus vulgaris* *Pseudomonasaeruginosa* *Serratia marcescens* *Stenotrophomonasmaltophilia*
Gram-positiveanaerobes: *Clostridiumdifficile*
Gram-negativeanaerobes: *Bacteroidesfragilis*
Others: *Chlamydia*spp. *Mycoplasma*spp. *Legionella*spp.

* All methicillin-resistant *S.aureus*are resistant to cefuroxime.

*Invitro*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 m^2 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 unchanged by glomerular filtration and renal 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 m^2 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. $C1_{cr}$ <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

None.

6.2 Incompatibilities

In the absence of other compatibility studies, this medicinal product must not be mixed with other medicinal products apart from those listed as compatible in section 6.6.

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

The pH of 2.74% w/v Sodium Bicarbonate Injection BP considerably affects the colour of the solution and therefore this solution is not recommended for the dilution of Cefuroxime.

However, if required, for patients receiving Sodium Bicarbonate Injection by infusion the Cefuroxime may be introduced into the tube of the giving set.

6.3 Shelf life

As packaged for sale: 30 months
In use: Following reconstitution with Water for Injections, chemical and physical in-use stability has been demonstrated for 48 hours at 2-8°C.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2-8°C, unless reconstitution/dilution has taken place in controlled and validated aseptic conditions.

6.4 Special precautions for storage

As packaged for sale: Do not store above 25°C. Keep the vial in the outer carton in order to protect from light.

In use: see 6.3.

6.5 Nature and contents of container

1.5 g (for intravenous injection) – Type III uncoloured glass vials with rubber stoppers in packs of 1, 10 or 50.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Instruction for constitution

Table 4. Addition volumes and solution/suspension concentrations, which may be useful when fractional doses are required.

Addition volumes and solution/suspension concentrations, which may be useful when fractional doses are required				
Vial size	Routes of administration	Amount of water to be added (mL)	Approximate cefuroxime concentration (mg/mL)**	Resulting product
1.5g	intramuscular intravenous bolus intravenous infusion	6 mL At least 15mL At least15 mL*	216 94 94	Suspension Solution Solution

** Reconstituted solution to be added to 50 or 100 ml of compatible infusion fluid (see information on compatibility, below)*
*** The resulting volume of the solution/suspension of cefuroxime in reconstitution medium is increased due the displacement factor of the drug substance resulting in the listed concentrations in mg/ml.*

As for all parenteral medicinal products, inspect the reconstituted solution or suspension visually for particulate matter and discoloration prior to administration.

Intramuscular injection: After addition of the specified amount of diluent for intramuscular injection, a suspension is formed.

Intravenous bolus injection or intravenous infusion: After addition of the specified amount of diluent for intravenous bolus or infusion, a clear solution is formed. The solution should only be used if it is clear and practically free from particles.

Solutions and suspensions range in colour from clear to yellow coloured depending on concentration, diluent and storage conditions used. When made up for intramuscular use, it becomes off-white and opaque. When made up for intravenous administration, it may be yellowish.

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 h at 4 °C or 6 h 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 h 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% Sodium Chloride Injection
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 Sodium Chloride Injection BP 0.9% w/v and in 5% Dextrose Injection is not affected by the presence of hydrocortisone sodium phosphate. Cefuroxime sodium has also been found compatible for 24 h at room temperature when admixed in i.v. infusion with:
Heparin (10 and 50 units/ml) in 0.9% Sodium Chloride Injection; Potassium Chloride (10 and 40 mEqL) in 0.9% Sodium Chloride Injection.

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

For single use. Discard any unused contents.

Contains no preservative.

7 MARKETING AUTHORISATION HOLDER

Flynn Pharma Limited
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Dublin 4
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8 MARKETING AUTHORISATION NUMBER

PA1226/009/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23 June 2000

Date of last renewal: 22 June 2015

10 DATE OF REVISION OF THE TEXT

August 2024