

# Cefuroxime Panpharma 750 mg

## 1. NAME OF THE MEDICINAL PRODUCT

Cefuroxime Panpharma 750 mg  
Powder for Solution for Injection /Infusion

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Vials containing 750 mg sterile Cefuroxime as Cefuroxime sodium.  
Sodium content per vial: 38.62 mg

## 3. PHARMACEUTICAL FORM

Cefuroxime is a white to faintly-yellow powder to which appropriate amounts of water are added.

## 4. CLINICAL PARTICULARS

### 4.1 Indications

#### ***Respiratory Tract Infections***

For example, acute and chronic bronchitis, infected bronchiectasis, bacterial pneumonia, lung abscess and post-operative chest infections.

#### ***Ear, Nose and Throat Infections***

For example, sinusitis, tonsillitis, pharyngitis and otitis media.

#### ***Urinary Tract Infections***

For example, acute and chronic pyelonephritis, cystitis and asymptomatic bacteriuria.

#### ***Soft Tissue Infections***

For example, cellulitis, erysipelas, peritonitis and wound infections.

#### ***Bone and Joint Infections***

For example, osteomyelitis and septic arthritis.

#### ***Obstetric and Gynecological Infections; Pelvic Inflammatory diseases; Gonorrhoea***

Particularly when penicillin is unsuitable.

#### ***Other Infections***

Including septicemia and meningitis.

#### ***Prophylaxis***

Against infection in abdominal, pelvic, orthopedic, cardiac, pulmonary, oesophageal and vascular surgery where there is increased risk of infection.

## 4.2 Dosage and Administration

### GENERAL DOSAGE RECOMMENDATIONS

#### *Adults*

Many infections will respond to 750 mg three times daily by IM or IV injection. For more severe infections, this dose should be increased to 1.5 g three times daily. IV. The frequency of IM or IV injections can be increased to six-hourly if necessary, giving total doses of 3 g to 6 g daily.

#### *Infants and Children*

Doses of 30 to 100 mg/kg/day given as three or four divided doses. A dose of 60 mg/kg/day will be appropriate for most infections.

#### *Neonates*

Doses of 30 to 100 mg/kg/day given as two or three divided doses. In the first weeks of life the serum half-life of cefuroxime can be three to five times that in adults.

### OTHER:

#### *Gonorrhoea*

1.5 g should be given as a single dose. This may be given as 2x750 mg injections (intramuscularly) into different sites, e.g. each buttock.

#### *Meningitis*

Cefuroxime is suitable for sole therapy of bacterial meningitis due to sensitive strains.

The following doses are recommended:

#### *Infants and Children*

200 to 240 mg/kg/day IV in three or four divided doses. This dosage may be reduced to 100 mg/kg/day IV after three days or when clinical improvement occurs.

#### *Neonates*

The initial dosage should be 100 mg/kg/day IV. A reduction to 50 mg/kg/day IV may be made when clinically indicated.

#### *Adults*

3 g IV every eight hours. Data are not yet sufficient to recommend a dose for intrathecal administration.

#### *Prophylaxis*

The usual dose is 1.5 g IV with induction of anaesthesia for abdominal, pelvic and orthopedic operations, but may be supplemented with two 750 mg IM doses 8 and 16 hours later. In cardiac, pulmonary, oesophageal and vascular operations, the usual dose is 1.5 g IV with induction of anaesthesia continuing with 750 mg IM three times daily for a further 24 to 48 hours.

#### *In Total Joint Replacement*

1.5 g cefuroxime powder may be mixed dry with each pack of methyl methacrylate cement polymer before adding the liquid monomer.

### ***Dosage in Impaired Renal Function***

Cefuroxime is 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. However, it is not necessary to reduce the standard dose (750 mg-1.5 g three times daily) until the creatinine clearance falls to 20 ml/min or below. In adults with marked impairment (creatinine clearance 10 to 20 ml/min) 750 mg twice daily is

recommended and with severe impairment (creatinine clearance <10 ml/min) 750 mg once daily is

adequate. For patients on haemodialysis a further 750-mg dose should be given IV or IM at the end of each dialysis. In addition to parenteral use, cefuroxime can be incorporated into the peritoneal dialysis fluid, usually 250 mg for every 2 litres of dialysis fluid given IV.

### ***Dosage in Continuous Arteriovenous Haemodialysis (CAVHD) or Haemofiltration (CAVH)***

For patients in renal failure on continuous arteriovenous haemodialysis or highflux haemofiltration in intensive therapy units a suitable dosage is 750 mg twice daily. For low-flux haemofiltration follow

the dosage recommended under *Dosage in Impaired Renal Function*.

## **ADMINISTRATION**

### ***Intramuscular***

Add 3 ml Water for Injections to 750 mg cefuroxime. Shake gently to produce an opaque suspension.

### ***Intravenous***

Dissolve cefuroxime in Water for Injections using at least 6 ml for 750 mg. For short intravenous infusion (e.g. up to 30 minutes), 1.5 g may be dissolved in 50 ml-100 ml Water for Injections. These solutions may be given directly into the vein or introduced into the tubing of the giving set if the patient is receiving parenteral fluids. Cefuroxime is compatible with the more commonly used intravenous fluids (see Pharmaceutical Precautions).

## **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 beta-lactam 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 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.

#### Intracameral use and eye disorders

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-abdominal infections

Due to its spectrum of activity, cefuroxime is not suitable for the treatment of infections caused by Gram-negative non-fermenting bacteria or by *Bacteroides fragilis* (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 750 mg vial:

This medicinal product contains 38.62 mg sodium per vial, equivalent to 1.9 % of the WHO recommended maximum daily intake of 2 g sodium for an adult.

#### **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 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: 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 Panpharma 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  $\geq 1/10$ ; 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).

<b>System organ class</b>	<b>Common</b>	<b>Uncommon</b>	<b>Not known</b>
<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 Stevens-Johnson 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.

Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form

<https://sideeffects.health.gov.il/>

## **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 beta-lactamases including (but not limited to) extended-spectrum beta-lactamases (ESBLs), and Amp-C enzymes, that may be induced or stably derepressed 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.

#### 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)	
	<u>Susceptible</u>	<u>Resistant</u>
<i>Enterobacteriaceae</i> <sup>1</sup>	≤8 <sup>2</sup>	>8
<i>Staphylococcus</i> spp.	Note <sup>3</sup>	Note <sup>3</sup>
<i>Streptococcus</i> A, B, C and G	Note <sup>4</sup>	Note <sup>4</sup>
<i>Streptococcus pneumoniae</i>	≤0.5	>1
<i>Streptococcus</i> (other)	≤0.5	>0.5
<i>Haemophilus influenzae</i>	≤1	>2
<i>Moraxella catarrhalis</i>	≤4	>8
Non-species related breakpoints <sup>1</sup>	≤4 <sup>5</sup>	>8 <sup>5</sup>
<sup>1</sup> The cephalosporin breakpoints for <i>Enterobacteriaceae</i> will detect all clinically important resistance mechanisms (including ESBL and plasmid mediated AmpC). Some strains that produce beta- lactamases are susceptible or intermediate to 3 <sup>rd</sup> or 4 <sup>th</sup> 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. <sup>2</sup> Breakpoint relates to a dosage of 1.5 g × 3 and to <i>E. coli</i> , <i>P. mirabilis</i> and <i>Klebsiella</i> spp. only <sup>3</sup> Susceptibility of staphylococci to cephalosporins is inferred from the methicillin susceptibility except for ceftazidime and cefixime and cefibuten, which do not have breakpoints and should not be used for staphylococcal infections. <sup>4</sup> The susceptibility of streptococcus groups A, B, C and G to cephalosporins is inferred from the benzylpenicillin susceptibility. <sup>5</sup> 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*.

<b>Commonly susceptible species</b>
<u>Gram-positive aerobes:</u> <i>Staphylococcus aureus</i> (methicillin-susceptible) \$ <i>Streptococcus pyogenes</i> <i>Streptococcus agalactiae</i>
<u>Gram-negative aerobes:</u> <i>Haemophilus parainfluenzae</i> <i>Moraxella catarrhalis</i>
<b>Microorganisms for which acquired resistance may be a problem</b>
<u>Gram-positive aerobes:</u> <i>Streptococcus pneumoniae</i> <i>Streptococcus mitis</i> (viridans group)
<u>Gram-negative aerobes:</u> <i>Citrobacter</i> spp. not including <i>C. freundii</i> <i>Enterobacter</i> spp. not including <i>E. aerogenes</i> and <i>E. cloacae</i> <i>Escherichia coli</i> <i>Haemophilus influenzae</i> <i>Klebsiella pneumoniae</i> <i>Proteus mirabilis</i> <i>Proteus</i> spp. not including <i>P. penneri</i> and <i>P. vulgaris</i> <i>Providencia</i> spp. <i>Salmonella</i> spp.
<u>Gram-positive anaerobes:</u> <i>Peptostreptococcus</i> spp. <i>Propionibacterium</i> spp.
<u>Gram-negative anaerobes:</u> <i>Fusobacterium</i> spp. <i>Bacteroides</i> spp.
<b>Inherently resistant microorganisms</b>
<u>Gram-positive aerobes:</u> <i>Enterococcus faecalis</i> <i>Enterococcus faecium</i>
<u>Gram-negative aerobes:</u> <i>Acinetobacter</i> spp. <i>Burkholderia cepacia</i> <i>Campylobacter</i> spp. <i>Citrobacter freundii</i> <i>Enterobacter aerogenes</i> <i>Enterobacter cloacae</i> <i>Morganella morganii</i> <i>Proteus penneri</i> <i>Proteus vulgaris</i> <i>Pseudomonas aeruginosa</i> <i>Serratia marcescens</i> <i>Stenotrophomonas maltophilia</i>
<u>Gram-positive anaerobes:</u> <i>Clostridium difficile</i>
<u>Gram-negative anaerobes:</u> <i>Bacteroides fragilis</i>
<u>Others:</u> <i>Chlamydia</i> spp. <i>Mycoplasma</i> spp. <i>Legionella</i> 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<sub>max</sub> 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<sup>2</sup> 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 metabolized.

### 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 m<sup>2</sup> 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**

Nitrogen qs

### **6.2 Incompatibilities**

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

### **6.3 Shelf life**

The expiry date of the product is indicated on the packaging materials.  
Store below 25°C, protected from light and keep in its original package.

### **6.4 Shelf-life after reconstitution**

Once reconstituted with Water for Injections the product is stable for 6 hours at a temperature below 25 °C and for 48 hours at a temperature between 2-8 °C.

### **6.5 Shelf-life after dilution**

The 30 mg/ml solutions of Cefuroxime in Water for Injections, NaCl 0.9%, Dextrose 5% were demonstrated to be physically compatible with no Cefuroxime loss in 24 hours at 25°C and 72 hours at 2°-8°C.  
From a microbiological point of view, the product must be used immediately. If not used immediately, in-use storage times and conditions prior to use are the only responsibility of the user and would not be longer than 24 hours at temperature ranging from +2°C and +8°C.

### **6.6 Nature and contents of container**

Colourless Glass type III vials with red chlorobutyl rubber (EP quality) with aluminum cap.  
Pack sizes: Cefuroxime Panpharma 750 mg – Pack of 10 vials

## **7 MANUFACTURER:**

Panpharma Laboratories, France.

## **8 LICENSE HOLDER AND IMPORTER:**

Pharmalogic Ltd., P.O.B. 3838, Petach Tikva 4951623.

## **9 REGISTRATION NO.:**

129-73-30873-00