SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

CEFAKS 750 mg IM/IV Powder for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial contains
Active substance:
Cefuroxime 750 mg (as cefuroxime sodium)

Excipient(s):
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder and solvent for solution for injection
White to cream-colored powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

CEFAKS is indicated in the treatment of infections caused by susceptible strains of certain microorganisms listed below:

1. Lower respiratory tract infections, including pneumonia, caused by *Streptococcus pneumoniae*, *Haemophilis influenzae* (including ampicillin-resistant strains), *Klebsiella* spp., *Staphylococcus aureus* (penicillinase producing and non-producing strains), *Streptococcus pyogenes* and *Escherichia coli.*
2. Urinary and genital system infections: *Escherichia coli* and *Klebsiella* spp.
3. Skin and soft tissue infections: methicillin-susceptible *Staphylococcus aureus* (penicillinase producing and non-producing strains), *Streptococcus pyogenes*, *Escherichia coli, Klebsiella* spp. and *Enterobacter spp*.
4. Septicemia: When used as IV (not intramuscular use) *Staphylococcus aureus* (penicillinase producing and non-producing strains), *Streptococcus pneumoniae, Escherichia coli, Haemophilis influenzae* (including ampicillin-resistant strains) and *Klebsiella* spp.
5. Meningitis: When used as IV (not intramuscular use) *Streptococcus pneumoniae*, *Haemophilis influenzae* (including ampicillin-resistant strains), Neisseria meningitides and methicillin-susceptible *Staphylococcus aureus* (penicillinase producing and non-producing strains).
6. Gonorrhea: disseminated and uncomplicated gonococcal infections in both men and women associated with *Neisseria gonorrhoeae*.
7. Bone and joint infections: *Staphylococcus aureus* (penicillinase producing and non-producing strains).

Prophylaxis: Pre-operative prophylactic CEFAKS administration reduces the incidence of various post-operative infections through preventing the growth of susceptible pathogenic bacteria in patients underwent surgical procedures classified as clean- or potentially- contaminated (e.g. vaginal hysterectomy).

In surgical procedures, the effective prophylactic administration of antibiotics depends on the timing of the drug. To achieve an effective concentration in the wound tissue, CEFAKS should be administered 1 to 1.5 hours before the operation. The dose can be repeated intraoperatively, which is expected to last longer.

Prophylactic administration of the drug is usually not required after surgical procedures. However, the prophylactic administration should be terminated within 24 hours following a surgical procedure. In open-heart surgery, pre-operative CEFAKS administration is efficacious in patients at risk of severe infection in the surgical site. Prolongation of the CEFAKS treatment up to 48 hours after the surgery is recommended in these patients. In the event of an infection, sampling should be carried out for cultivation to identify the causative microorganism and thus begin the appropriate antibiotic treatment.

4.2 Posology and method of administration

Cefuroxime sodium for injection is for intravenous (IV) and/or intramuscular (IM) administration.

No more than 750 mg should be injected at one intramuscular site.

Posology/frequency and duration of administration:
Adults
General use: Most of the infections will respond to 750 mg doses 3 times a day by IM or IV injection. For more severe infections, the dose should be increased to 1.5 g 3 times a day given IV. The frequency of IM or IV injections can be increased to 6-hourly if necessary, giving total doses of 3 g to 6 g daily. Where clinically indicated, various infections respond to 750 mg or 1.5 g twice daily by parenteral administration (IV or IM) followed by oral therapy.

Gonorrhea: 1.5 g should be given as a single dose. This may be given as 2×750 mg injections into different sites e.g. each buttock.

Meningitis: CEFAKS is suitable for the treatment of bacterial meningitis due to susceptible strains. Recommended dosage for adults: 3 g given IV every 8 hours.

Prophylaxis: The usual dose is 1.5 g given IV with induction of anesthesia for abdominal, pelvic and orthopedic operations, but may be supplemented with 2×750 mg IM doses 8 and 16 hours later. In cardiac pulmonary esophageal and vascular operations, the usual dose is 1.5 g given IV with induction of anesthesia continuing with 750 mg given IM 3 times a day for a further 24 to 48 hours.

In arthroplasty (total joint replacement) operations: cefuroxime powder at a total dose of 1.5 g may be mixed dry with each pack of methyl methacrylate cement polymer before adding the liquid monomer.

Consecutive Treatment:
Pneumonia: Following the injection of 1.5 g twice daily (given IV or IM) for 48-72 hours, the treatment is continued with 500 mg twice daily CEFAKS (cefuroxime sodium) oral therapy for 7 to 10 days.

Acute exacerbations of chronic bronchitis: Following the injection of 750 mg 2 or 3 times daily (given IV or IM) for 48-72 hours, the treatment is continued with 500 mg twice daily CEFAKS

(cefuroxime sodium) oral therapy for 5 to 10 days. Duration of both parenteral and oral therapy is determined by the severity of the infection and the clinical status of the patient.

In children:
General use: 30 to 100 mg/kg/day given IV in 3 or 4 divided doses for infants and children. A dose of 60 mg/kg/day is appropriate for most infections. 30-100 mg/kg/day given as 2 or 3 divided doses for neonates.

Meningitis: 150-250 mg/kg/day given IV in 3 or 4 divided doses for infants and children. Dosage for neonates should be 100 mg/kg/day given as IV.

Method of administration
Intramuscular: Add 1 ml of water for injections to 250 mg cefuroxime sodium or 3 ml of water for injections to 750 mg cefuroxime sodium. Shake gently to produce an opaque suspension.

Intravenous: Dissolve CEFAKS in water for injection using at least 2 ml for CEFAKS 250 mg, at least 6 ml for CEFAKS 750 mg and at least 15 ml for CEFAKS 1.5 g.

Intravenous Infusion: Dissolve 1.5 g cefuroxime sodium in 15 ml of water for injection. Add the dissolved cefuroxime sodium to 50 or 100 ml of a compatible infusion fluid. These solutions can be administered directly into the vein, or can be given to the patient by injecting it into the set if the patient is receiving parenteral fluids.

Additional information on special populations

Renal impairment:
Dosage in impaired renal function: Cefuroxime is excreted by the kidneys. Therefore, as with all such antibiotics, in patients with impaired renal function it is recommended that the dosage of CEFAKS should be reduced to compensate for its slower excretion. However, it is not necessary to reduce the standard dose (750 mg-1.5 mg 3×1) until the creatinine clearance falls to or below 20 ml/min. In adults with marked impairment (creatinine clearance 10-20 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 hemodialysis, a further 750 mg dose by IV or IM should be given at the end of each dialysis. In addition to the parenteral administration cefuroxime may be added into peritoneal dialysis fluid (usually 250 mg into each 2 liters of the dialysis fluid). For patients in renal failure on continuous arteriovenous hemodialysis or high-flux hemofiltration in intensive therapy units, a suitable dosage is 750 mg twice daily. For low-flux hemofiltration follow the dosage recommended under impaired renal function.

Hepatic impairment:
No data available.

Pediatric population:
General use: In infants and children, doses of 30 to 100 mg/kg/day are given as 3-4 divided doses. A dose of 60 mg/kg/day will be appropriate for most infections. In neonates, doses of 30 to 100 mg/kg/day are given as 2-3 divided doses.

Meningitis: 150 to 250 mg/kg/day given IV in 3-4 divided doses for infants and children. Dosage for neonates should be 100 mg/kg/day given as IV.

Geriatric population:
No data available.

4.3 Contraindications

It is contraindicated in patients with known hypersensitivity to cefuroxime or the other ingredients the drug contains.

It is contraindicated in individuals with a history of severe hypersensitivity (*e.g.* anaphylactic shock) to beta-lactam antibiotics (such as penicillins, monobactams, carbapenems).

4.4 Special warnings and precautions for use

Before therapy with is instituted, careful inquiry should be made to determine whether the patient has had previous hypersensitivity reactions to cephalosporins, penicillins, or other drugs. If this product is to be given to penicillin-sensitive patients, caution should be exercised because cross hypersensitivity among beta-lactam antibiotics has been clearly documented and may occur in up to 10% of patients with a history of penicillin allergy. If an allergic reaction occurs, the drug should be discontinued and appropriate therapy instituted. Serious acute hypersensitivity reactions may require treatment with epinephrine and other emergency measures, including oxygen, intravenous fluids, intravenous antihistamines, corticosteroids, pressor amines, and airway management, as clinically indicated.

Cephalosporin antibiotics at high dosage should be given with caution to patients receiving concurrent treatment with potent diuretics such as furosemide and aminoglycosides, as these combinations are suspected of adversely affecting renal function. Renal function should be checked in these patients, elderly patients, and patients who have previously had renal insufficiency (See section 4.2).

As with other therapeutic regimens used in the treatment of meningitis, mild or moderate hearing loss has been reported in a few patients treated with cefuroxime sodium.

Persistence of positive cerebrospinal fluid (CSF) cultures of *Haemophilus influenza* at 18-36 hours has been noted in some patients treated with cefuroxime sodium injection as with other antibiotic treatments; however, the clinical relevance of this is unknown.

With a sequential therapy regime the timing of change to oral therapy is determined by severity of the infection, clinical status of the patient and susceptibility of the pathogens involved. If there is no clinical improvement within 72 hours, then the parenteral course of treatment must be continued.

Glucose oxidase or hexokinase is recommended for determination of blood / plasma glucose level in patients receiving cefuroxime sodium, as a false negative result may be obtained in the ferricyanide test.

Use of cefuroxime may result in the overgrowth of *Candida* as with the other antibiotics. 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.

Cases of pseudomembranous colitis, which may range in severity from mild to severe, have been reported with the use of antibiotics. Therefore, it is important to consider this diagnosis in patients who present with diarrhea during or subsequent to the administration of any antibiotics. Following

the diagnosis of pseudomembranous colitis appropriate therapy should be instituted. Mild cases of pseudomembranous colitis usually respond to discontinuation of the drug alone. However, in moderate to severe cases consideration should be given to management with fluids and electrolytes, protein supplementation, and treatment with an antibiotic effective against *Clostridium difficile*. If prolonged or severe diarrhea, or stomach cramps occur in the patient the treatment should be discontinued and the patient further examined.

This medicinal product contains 1.8 mmol (or 42.56 mg) sodium per 750 mg dose. This should be considered for patients who are on a controlled sodium diet.

4.5 Interactions with other medicinal products and other forms of interaction

In common with other antibiotics, cefuroxime may affect the gut flora, leading to lower estrogen reabsorption and reduced efficacy of combined oral contraceptives.

CEFAKS does not interfere in enzyme-based tests for glycosuria.

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.

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.

Concomitant use with oral anticoagulants may give rise to increased international normalized ratio (INR).

Cephalosporin antibiotics at high dosage should be given with caution to patients receiving concurrent treatment with potent diuretics such as furosemide or aminoglycosides, as renal impairment has been reported with these combinations.

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.

It does not interfere in the alkaline picrate assay for creatinine.

4.6 Fertility, pregnancy and lactation

General recommendation
Pregnancy category is B.

Women of child-bearing potential/Contraception
In common with other antibiotics, cefuroxime may affect the gut flora, leading to lower estrogen reabsorption and reduced efficacy of combined oral contraceptives.

Pregnancy
There are limited amounts of data from the use of cefuroxime in pregnant women. Animal studies have revealed no direct or indirect harmful effects on pregnancy/embryonal/fetal development/ parturition or post-natal development. Caution should be exercised when prescribing to pregnant

woman.

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.

Lactation
Cefuroxime is excreted in human milk in small quantities. Adverse reactions at therapeutic doses are not expected, although a risk of diarrhea and fungus infection of the mucous membranes cannot be excluded.

The decision whether to continue breastfeeding during treatment with cefuroxime or to discontinue treatment should be made after careful benefit/risk assessment.

Reproduction ability / Fertility:
No data are available.

4.7 Effects on ability to drive and use machines

None reported.

4.8 Undesirable effects

Adverse drug reactions of cefuroxime sodium are generally mild and transient.

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.

The following convention has been used 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),
Not known (cannot be estimated from the available data).

Infections and infestations
Very common: Candida overgrowth, overgrowth of *Clostridium difficile*

Blood and lymphatic system disorders
Common: Eosinophilia, neutropenia, decreased hemoglobin concentration
Uncommon: Positive Coomb's test, leucopenia,

Not known: Thrombocytopenia, hemolytic anemia
Immune system disorders
Not known: Drug fever, interstitial nephritis, anaphylaxis, cutaneous vasculitis

Gastrointestinal disorders
Uncommon: Gastrointestinal disturbance
Not known: Pseudomembranous colitis (see section 4.4)

Hepato-biliary disorders
Common: Transient rise in liver enzymes
Uncommon: Transient rise in bilirubin

Skin and subcutaneous tissue disorders:
Hypersensitive reactions including reactions in below:
Uncommon: Skin rash, urticaria, pruritus
Not known: Erythema multiforme, toxic epidermal necrolysis (exanthematic necrolysis), Stevens-Johnson syndrome, angioneurotic edema

Renal and urinary disorders
Not known: Elevations in serum creatinine and/or blood urea nitrogen and decreased creatinine clearance (see section 4.4)

General disorders and administration site conditions
Common: Injection site reactions which may include pain, thrombophlebitis

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 hemolytic anemia.

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.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization 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 the national reporting system.

4.9 Overdose

Overdose can lead to neurological sequelae including encephalopathy, convulsion and coma. Serum levels of cefuroxime can be reduced by hemodialysis and peritoneal dialysis.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic group: Second-generation cephalosporins
ATC code: J01DC02

Cefuroxime is a well-characterized and effective antibacterial agent, which has bactericidal activity against a wide range of common pathogens, including β-lactamase producing strains.

Cefuroxime has good stability to bacterial β-lactamase, and consequently is active against many ampicillin-resistant or amoxicillin-resistant strains. The bactericidal action of cefuroxime results from inhibition of cell wall synthesis by binding to essential target proteins.

The prevalence of acquired resistance is geographically and time dependent and for select species may be very high. Local information on resistance is desirable, particularly when treating severe infections.

***In vitro* susceptibility of micro-organisms to Cefuroxime** Where clinical efficacy of cefuroxime has been demonstrated in clinical trials this is indicated with an asterisk (*).
Commonly Susceptible Species
Gram-Positive Aerobes: *Staphylococcus aureus (methicillin-susceptible)** Coagulase negative *Staphylococcus (methicillin-susceptible)* *Streptococcus pyogenes** Beta-hemolytic streptococcus
Gram-Negative Aerobes: *Haemophilus influenzae* including ampicillin resistant strains* *Haemophilus parainfluenzae** *Moraxella catarrhalis** *Neisseria gonorrhoeae* including penicillinase and non-penicillinase producing strains* *Neisseria meningitidis* *Shigella spp.*
Gram-Positive Anaerobes: *Peptostreptococcus* spp. *Propionibacterium* spp.
Spirochetes: *Borrelia burgdorferi**
Organisms for which acquired resistance may be a problem
Gram-Positive Aerobes: *Streptococcus pneumoniae** Viridans group streptococcus
Gram-Negative Aerobes: *Bordetella pertussis* *Citrobacter* spp. not including *C. freundii* *Enterobacter* spp. not including *E. aerogenes* and *E. cloacae* *Escherichia coli** *Klebsiella* spp. including *K. pneumoniae** *Proteus mirabilis* *Proteus* spp. not including *P. penneri* and *P. vulgaris* *Providencia* spp.

Salmonella spp.
Gram-Positive Anaerobes: Clostridium spp. not including *C. difficile*
Gram-Negative Anaerobes: Bacteroides spp. not including *B. fragilis* *Fusobacterium* spp.
Inherently resistant organisms
Gram-Positive Aerobes: *Enterococcus* spp. including *E. faecalis* and *E. faecium* *Listeria monocytogenes*
Gram-Negative Aerobes: *Acinetobacter* spp. *Burkholderia cepacia* *Campylobacter* spp. *Citrobacter freundii* *Enterobacter aerogenes* *Enterobacter cloacae* *Morganella morganii* *Proteus penneri* *Proteus vulgaris* *Pseudomonas* spp. including *P. aeruginosa* *Serratia* spp. *Stenotrophomonas maltophilia*
Gram-Positive Anaerobes: *Clostridium difficile*
Gram-Negative Anaerobes: *Bacteroides fragilis*
Others**:** *Chlamydia* species *Mycoplasma* species *Legionella* species

5.2 Pharmacokinetic properties

General properties

Absorption:

After intramuscular (IM) injection of cefuroxime to normal volunteers, the mean peak serum concentrations ranged from 27 to 35 mcg/ml for a 750 mg dose and from 33 to 40 mcg/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 mcg/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 33-50%, depending on the methodology used.

Concentrations of cefuroxime in excess of the minimum inhibitory levels for common pathogens can be achieved in the bone, synovial fluid and aqueous humor. 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 IM or IV injection is approximately 70 minutes. In the first weeks of life the serum half-life of cefuroxime can be 3-5 times that in adults. Concurrent administration of probenecid prolongs the excretion of the antibiotic and produces an elevated peak serum level. There is almost complete recovery (85-90%) of unchanged cefuroxime in the urine within 24 hours of administration, the major part being eliminated in the first 6 hours. Serum levels of cefuroxime can be reduced by dialysis.

Characteristics in patients
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).

Pediatric:
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. C1cr <20 ml/min) 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 hemodialysis 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

No data are available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of other ingredients

Solvent:
Water for injections

6.2 Incompatibilities

CEFAKS should not be mixed in the syringe with aminoglycoside antibiotics. The pH of 2.74% w/v sodium bicarbonate injection BP considerably affects the color of the solution and therefore is not recommended for the dilution of CEFAKS. However, if required, for patients receiving sodium bicarbonate injection by infusion the CEFAKS may be introduced into the tube of the giving set.

6.3 Shelf life

48 months.

6.4 Special precautions for storage

When it is dry powder, CEFAKS should be store at room temperature below 25°C.

After reconstitution, all injectable vials should preferably be used immediately. However, reconstituted solutions maintain their effectiveness for 5 hours at room temperature below 25°C, for 48 hours at 2-8°C.

Protect from light.

Color darkening can be seen in the reconstituted solution of CEFAKS during storage.

6.5 Nature and contents of container

A colorless glass vial (Type III) sealed with a rubber stopper and an aluminum flip off cap and a colorless glass ampoule (Type I) containing 6 ml water for injections.

Each cardboard box contains 1 vial and 1 solvent ampoule.

6.6 Special precautions for disposal and other handling

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 CEFAKS 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. CEFAKS is compatible with the more commonly used intravenous infusion fluids. It will retain potency for up to 24 hours at room temperature in:

- Sodium Chloride Injection BP 0.9% w/v,
- 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,
- Lactated Ringer's Injection USP,
- M/6 Sodium Lactate Injection,
- Compound Sodium Lactate Injection BP (Hartmann's Solution).

The stability of CEFAKS in Sodium Chloride Injection BP 0.9% w/v and in 5% Dextrose Injection is not affected by the presence of hydrocortisone sodium phosphate. CEFAKS is compatible with aqueous solutions containing up to 1% lidocaine hydrochloride. CEFAKS is compatible for 24 hours at room temperature when mixed with the following intravenous infusions:
- Heparin (10 and 50 units/ml) in 0.9% Sodium Chloride Injection,
- Potassium Chloride (10 and 40mEqL) in 0.9% Sodium Chloride Injection.

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

7. MARKETING AUTHORIZATION HOLDER

DEVA Holding A.Ş.
Halkalı Merkez Mah. Basın Ekspres Cad. No:1
34303 Küçükçekmece - ISTANBUL/TURKEY

8. MARKETING AUTHORIZATION NUMBER

203/84

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION

Date of first authorization : 01.03.2004
Date of last renewal : 03.12.2010

10. DATE OF REVISION OF THE TEXT

18.12.2020