Risk Management Plan (EU-RMP)

Cefuroxim B. Braun 750 mg
Cefuroxim B. Braun 1500 mg

Part VI: Summary of activities in the risk management plan by product

Part VI.2: Elements for a public summary

Part VI.2.1: Overview of disease epidemiology

Cefuroxim B. Braun 750 mg and Cefuroxim B. Braun 1500 mg is indicated for the treatment of infections of the lungs or chest (community acquired pneumonia and acute exacerbation of chronic bronchitis), the urinary tract (such as complicated urinary tract infections), the skin and soft tissue or the abdomen caused by bacteria. The medicinal products are also used to prevent infections during surgery.

Infections of the lung or chest
Community-acquired pneumonia (CAP) is a common and potentially serious illness. It is associated with considerable diseasedness and death, particularly in high risk patients such as the elderly. The overall rate of CAP in adults is approximately 5.16 to 6.11 cases per 1,000 persons per year and the rate of CAP increases with increasing age. There is seasonal variation, with more cases occurring during the winter months and the rates of pneumonia are higher for men than for women (Marrie 2012).
Based on data collected in the United States, approximately 4 % of the population was diagnosed with chronic bronchitis although these statistics may underestimate the prevalence of chronic obstructive pulmonary disease by as much as 50 %, because many patients underreport their symptoms, and their conditions remain undiagnosed (Fayyaz et al. 2011). In Germany, the prevalence (the proportion of individuals in a population having the disease/characteristic) of chronic bronchitis is estimated to be 10 – 15 % in adults (Antwerpes 2012).

Complicated urinary tract infections, including kidney infection (pyelonephritis)
A complicated urinary tract infection (UTI) is an urinary infection occurring in a patient with a structural or functional abnormality of the genito-urinary tract e.g. obstructions of the ureter (narrowing of the urethra, enlarged prostate) or impaired voiding; instrumentation/devices such as indwelling urethral catheter, stents or urological procedures; metabolic abnormalities such as renal failure. The quantitative criteria of at least 10^8 colony-forming units (cfu)/L (at least 10^5 cfu/mL) is generally appropriate for the microbiological identification of complicated urinary infection. Urological devices that remain in their position (*in situ*), such as indwelling urethral catheters, ureteric stents and nephrostomy tubes, rapidly become coated with a biofilm. Beside these patients, further risk groups include males, pregnant women, patients with diabetes mellitus, with a suppressed immune system or with urinary stones. Additional risk factors are surgery of the urinary tract and hospitalisation. Overall, complicated urinary

infections occur in both women and men, and in any age group. (Nicolle et al. 2005, Neal 2008).
About 2 % of patients with UTIs have complicated infections. If factors that can increase the severity of a renal infection are included, the frequency of complicated infections is even about 8 % (Norrby 2012).

Infections of the skin and soft tissue
Approximately 7 % to 10 % of hospitalised patients are affected by skin and soft tissue infections (SSTIs) and they are very common in the emergency care setting (Ki et al. 2008)). Since the late 1990s, the frequency of SSTIs has increased significantly, predominately because of an increase in infections caused by resistant bacteria. *Staphylococcus aureus* remains the most common pathogen isolated from complicated SSTIs (May 2011).

Prevention of intra-abdominal infections
Intra-abdominal infection continues to be one of the major challenges in general surgery. Whilst the term "peritonitis" means an inflammation of the peritoneum regardless of its etiology, intra-abdominal infections encompass all forms of bacterial peritonitis, of intra-abdominal abscesses and of infections of intra-abdominal organs. The true incidence of secondary bacterial peritonitis is difficult to assess but it is mainly caused by perforation of hollow viscus (e.g. intestines) (Farthmann et al. 1998). Surgical site infections (SSIs) are the most common hospital-acquired infections among surgical patients (Junker et al. 2012). The occurrence of SSIs depends on several parameters such as the patient's condition and degree of contamination. In the United States, an individual subjected to a major operation is expected to carry a 2 % risk of SSI. This rate is substantially higher if the individual undergoes colorectal surgery, with a current rate of 5 % to 30 % for SSIs in colorectal operations (Murray et al. 2010).
Many studies have been carried out to investigate the suitability of cefuroxime for perioperative antibiotic prophylaxis. The data clearly show that cefuroxime is suitable to avoid secondary peritonitis.

Part VI.2.2: Summary of treatment benefits

Infections of the lungs or chest
Although the causes of lung infections such as pneumonia vary by geographic region, infections with bacteria named *Streptococcus pneumoniae* is the most common cause of pneumonia worldwide. Furthermore, these infections may also be associated with death. In 2005, over 60,000 deaths due to pneumonia occurred in the United States. Death rate is highest in patients with community-acquired pneumonia who have to stay in the hospital. The 30-day death rate is of up to 23 percent in such patients. Given the aging population in several regions worldwide, it is expected that the burden of CAP will increase (Marrie 2012). Among the specific group of medicines called cephalosporins cefuroxime is a well-established and important medicine used to treat CAP. Cefuroxime is very effective for the treatment of infections caused by methicillin-susceptible *Staphylococcus aureus.* In patients with moderate or severe exacerbation of chronic bronchitis without an infection caused by a bacterium called *Pseudomonas aeruginosa,* without areas of the lung that are permanently and abnormally widened (bronchiectasis) and without mechanical ventilation,

injection/infusion with cephalosporins such as cefuroxime is recommended as stated in official guideline documents (AWMF online 2005).

Complicated urinary tract infections, including pyelonephritis
Urinary tract infections (UTIs) are among the most frequent infectious diseases. The designation of complicated urinary tract infections is used when an UTI occurs in an individual in whom specific anatomical or functional abnormalities related to the urinary tract (e.g. obstruction or incomplete voiding) are believed to result in an infection that will be more difficult to treat than an uncomplicated infection (Brown et al. 2007). In line with current guideline documents, infusions/injections of a group of cephalosporins including cefuroxime is very effective for the treatment of complicated urinary tract infections caused by bacteria called Gram-negative bacteria such as *E. coli, Klebsiella pneumoniae* or *Proteus mirabilis* and Gram-positive bacteria such as *Staphylococci* and *Streptococci* (Grabe 2011).

Infections of the skin and soft tissues and abdominal infections
In recent years the frequency of infections caused by resistant bacteria increased which made treatment with antibacterial medicines more difficult. However and especially for skin and soft tissue infections affecting the head and hand, cefuroxime is the recommended empirical medicine of choice if infections with *Haemophilus* are suspected and in case of severe courses of the disease (Ki et al. 2008).

Prevention of intra-abdominal infections
Intra-abdominal infection continues to be one of the major challenges in general surgery. Surgical site infections are associated with increased hospital length of stay, increased risk of death, and decreased health-related quality of life. With the introduction of antibacterial medicines used for the prevention of infections accompanied with surgery, the frequency of these infections markedly decreased. Cefuroxime – often in combination with further antibacterial medicines – was successful against several bacterial strains and is recommended for the prevention of infections associated with several surgical interventions (Junker et al. 2012, Gordillo et al. 2008). With regard to mild to moderate infections of the abdomen, combination treatment with cefuroxime is assigned to be preferable to other treatment regimens as stated in official and current guideline documents (Solomkin et al. 2010).

Part VI.2.3: Unknowns relating to treatment benefits

Cefuroxime is an antibiotic. As acquired resistance may vary geographically and with time, consideration should be given to any new official (local) information/guidelines.

Part VI.2.4: Summary of safety concerns

The important risks identified for Cefuroxim B.Braun 750 mg and Cefuroxim B.Braun 1500 mg presented below are also adequately described in the respective product information.

Risk	What is known	Preventability
Hypersensitivity	Hypersensitivity reactions have been reported in less than 1% of the patients treated with Cefuroxime for Injection, USP and include rash (1 in 125). Pruritus and urticaria occurred in fewer than 1 in 250 patients, and, as with other cephalosporins, rare cases of anaphylaxis, drug fever, erythema multiforme, interstitial nephritis, toxic epidermal necrolysis, and Stevens-Johnson syndrome have also been observed (Cefuroxime for Injection, USP). Skin hypersensitivity and pyrexia were noted only in 26 cases (2.5%) of the total 1,057 cases treated with cefuroxime in open and double-blind clinical studies[1]. Serum sickness-like reactions (type III hypersensitivity reaction) can rarely observed after multiple courses of antibiotics. It has been shown to be a risk factor and may increase the frequency of serum sickness-like reactions[2]. Bilateral renal cortical necrosis developed after receiving 7 doses cefuroxime over 4 treatment days. The proposed mechanism of renal cortical necrosis is a hypersensitivity reaction[3]. In addition cefuroxime induced lymphomatoid hypersensitivity reaction[4]. ***1.*** *Nakagawa K.: Review: New antibiotics series I: Cefuroxime. Jpn.J.Antibiot. 1982; 35(2): 283-295.* ***2.*** *Baniasadi S., Fahimi F., Mansouri D.: Serum sickness-like reaction associated with cefuroxime and ceftriaxone. The Annals of Pharmacotherapy 2007; 41: 1318-1319.* ***3.*** *Manley H.J., Bailie G.R., Eisele G.: Bilateral renal cortical necrosis associated with cefuroxime axetil.*	· Yes, by not receiving Cefuroxim B.Braun 750 mg and Cefuroxim B.Braun 1500 mg. Of note, the prohibition of treatment in affected patients is adequately described in the respective product information. · Yes, careful evaluation of each patient's medical history before beginning of treatment is highly advisable.

	Clinical Nephrology 1998; 49(4): 268-270. ***4.*** *Saed S.A.M., Bazza M., Zaman M., Ryatt K.S.: Cefuroxime induced lymphomatoid hypersensitivity reaction. Postgrad.Med.J. 2000; 76: 577-579.*	
Drug drug interactions (furosemide, aminoglycosides, probenecid)	Concomitant treatment with furosemide did not impair renal function. In 2 studies no evidence of nephrotoxicity was found[1,2]. Renal function remained constant and no change in the urine sediment was observed. It appears, that cefuroxime is a safe drug, even in patients with chronic renal insufficiency and furosemide treatment, if an appropriate reduction in dose is made[1]. Currently one case of toxic epidermal necrolysis was described. It developed 18 days of the initiation of cefuroxime axetil therapy for urinary tract infection in a 73-year-old woman with chronic renal failure (no previous history of allergic diathesis). Because the patient was also taking furosemide for chronic renal failure, the possible unfavourable interactions between the two drugs could be hypothesised. Therefore, awareness of the possible drug interaction is necessary, especially when given in conditions of their altered pharmacokinetics as in case of chronic renal failure[3]. ***1.*** Walstad R.A., Nilsen O.G., Berg K.J.: Pharmacokinetics and clinical effects of cefuroxime in patients with severe renal in sufficiency. Eur.J.Clin Pharmacology 1983; 24: 391-398. ***2.*** Trollfors B., Suurkula M., Price J.D., Norrby R.: Renal function during cefuroxime treatment in patiets with pre-existing renal impairment. Journal of Antimicrobial Chemotherapy 1980; 6: 665-670. **3**. Grgurevic I., Pejša V., Morovic-Vergles J., Dobric I., Gasparovic V., Tudoric N.: Fatal toxic epidermal	· Yes, for the use of Cefuroxime 750 mg and 1500 mg a special warning is mentioned in the applicants SmPC as following: 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. · Yes, careful evaluation of each patient's medical history - especially with regard to the administered drugs - before start of treatment is highly advisable. · Yes, frequent monitoring of clinical state is advisable in patients with renal failure.

	necrolysis and severe granulocytopenia following therapy with cefuroxime. Acta Dermatovenerol.Croat. 2008; 16(3). 133-137.	
Overgrowth of non-susceptible microorganisms	The worldwide incidence of infections caused by several bacterial strains such as *Streptococcus pneumoniae* isolates resistant to penicillin and other antimicrobial agents has increased at an alarming rate during the past 2 decades. The clonal spread of non-susceptible strains from country to country and continent to continent is of great concern. Plasmid mediated AmpC b-lactamases represent a new threat. Cross-resistance between cefuroxime and several other β-lactam antibiotics, including amoxicillin, methicillin, penicillin and ampicillin and ciprofloxacine and cefpodoxine can also occur. Extended-Spectrum Beta-Lactamases (ESBLs) are enzymes that can be produced by bacteria making them resistant to cephalosporins e.g. cefuroxime, cefotaxime and ceftazidime - which are the most widely used antibiotics in many hospitals (HPA UK 2012).Cefuroxime resistance in *S. pneumoniae* and *H. influenzae* may be conferred by alterations in penicillin-binding proteins. In Enterobacteriaceae resistance to cefuroxime may be conferred by several mechanisms alone or in combination, including the production of some beta-lactamases (ESBLs, AmpC and others), porin loss and alteration in efflux pumps (EUCAST Cefuroxime 2010).	· Yes, special recommendation is mentioned in the applicants SmPC as following: Consideration should be given to official guidance on the appropriate use of antibacterial agents. And 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. · Yes, it is well known that for the safe use of antibiotics an antibiogram should be prepared before start of treatment to identify susceptible bacterial strains.
Interference with	There have been occasional	· Yes, for the use of Cefuroxime

diagnostic tests **Copper reduction test** **Ferricyanide test**	reports of decreased haemoglobin, or positive Coomb´s tests. A Coomb´s test was performed in 92 patients before and during or after treatment – 3 became positive[1]. **1:** Harding S. M.: Cefuroxime: Therapeutic success – clinical experience. Schweiz Rundschau Med. (Praxis) 1980; 69: 729-741.	750 mg and 1500 mg special warnings are mentioned in the applicants SmPC as following: 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.
Leukopenia/Neutropenia	In total 753 Cefuroxime axetil users are studied based on reports from FDA. Among them 22 patients (2.92%) have Neutropenia. Also observed was neutropenia (< 1500/mm^3) in 18% of 28 children treated for more than 5 days with cefuroxime[1]. **1:** Gold B., Rodriguez W.J.: Cefuroxime: Mechanism of action, antimicrobial activity, pharmacokinetics, clinical applications, adverse reactions and therapeutic indications. Pharmacotherapy. 1983; 3: 82-100.	· Yes, for the use of Cefuroxime 750 mg and 1500 mg special advise is given in section 4.8 of the applicants SmPC as following: 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. · Yes, careful evaluation of each patient's medical history before beginning of treatment is highly advisable. · Yes, frequent monitoring of clinical state is necessary, especially appropriate hematology tests should be made in hospitalised patients.
Haemolytic anaemia	Drug-induced immune haemolytic anaemia is rarely observed. It is a hypersensitivity reaction and the most commonly cited cause of drug-induced immune haemolytic anaemia has been receipt of second and third generation cephalosporin	· Yes, for the use of Cefuroxime 750 mg and 1500 mg special advise is given in section 4.8 of the applicants SmPC as following: 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

	antibiotics.	Coomb's test (which can interfere with cross matching of blood) and very rarely haemolytic anaemia. · Yes, frequent monitoring of clinical state is necessary, especially appropriate hematology tests should be made in hospitalised patients.
Thrombocytopenia	Drug-induced thrombocytopenia (DIT) is a relatively common clinical disorder. DIT can be distinguished from idiopathic thrombocytopenic purpura (ITP), a bleeding disorder caused by thrombocytopenia not associated with a systemic disease, based on the history of drug ingestion or injection and laboratory findings. DIT disorders can be a consequence of decreased platelet production (bone marrow suppression) or accelerated platelet destruction (especially immune-mediated destruction). However drug induced thrombocytopenia associated to cefurocime treatment is very rarely observed.	· Yes, for the use of Cefuroxime 750 mg and 1500 mg thrombocytopenia is listed in section 4.8 of the applicants SmPC. · Yes, careful evaluation of each patient's medical history before beginning of treatment is highly advisable. · Yes, frequent monitoring of clinical state is imperative to provide rapid identification and removal of the offending agent before clinically significant bleeding or, in the case of heparin, thrombosis occurs. · Yes, frequent monitoring of clinical state is necessary, especially appropriate hematology tests should be done in hospitalised patients.
Interstitial nephritis	Interstitial nephritis is also known as chemically induced nephritis. It can rarely be observed after administration of antibiotics such as cefuroxime as a result of hypersensitivity reaction to the antibiotic given.	· Yes, for the use of Cefuroxime 750 mg and 1500 mg the side effect is listed in section 4.8 of the applicants SmPC. · Yes, careful evaluation of each patient's medical history before beginning of treatment is highly advisable. Patients with known hypersensitivity to drugs should be frequently monitored and appropriate laboratory tests should be done.
Cutaneous vasculitis	Antibiotics have been the most common drugs reported to cause cutaneous vasculitis, especially β-lactams. Drugs may act as haptens and activate the immune response. It as a type of hypersensitivity reaction limited to the skin.	· Yes, for the use of Cefuroxime 750 mg and 1500 mg the side effect is listed in section 4.8 of the applicants SmPC. · Yes, careful evaluation of each patient's medical history before beginning of treatment is highly advisable. Patients with known hypersensitivity to drugs should be

		frequently monitored and appropriate laboratory tests should be done.
Erythema multiforme; Toxic epidermal necrolysis; Stevens-Johnson syndrome; Angioneurotic oedema	It is considered by some authors that Erythema multiforme being part of a spectrum of disease which includes, in order of severity, Erythema multiforme, Stevens-Johnson syndrome and toxic epidermal necrolysis (Lyell´s syndrome). All three skin deseases are very rare hypersensitivity complications of medications use. Erythema multiforme is a distinctive dermatological eruption featuring iris or target lesions. The minor form is an acute, self-limiting disease that affects the skin but mucous membranes little, if at all. The major form has more involvement of both skin and mucosa and is a potentially life-threatening condition. The estimated frequency for Stevens-Johnson syndrome is to be 1-2/million each year and 0.4-1.2/million each year for Lyell´s syndrome. More than 200 medications have been reported in association with Stevens-Johnson syndrome and Lyell´s syndrome.	· Yes, for the use of Cefuroxime 750 mg and 1500 mg the side effect is listed in section 4.8 of the applicants SmPC. · Yes, careful evaluation of each patient's medical history before beginning of treatment is highly advisable. · Yes, these adverse drug reactions usually develop within the first week of antibiotic therapy. Therefore careful monitoring of the health status of the patient is helpful to identify early symptoms of severe allergic reactions.
Transient rise in liver enzymes; Transient rise in bilirubin	Most cases of drug induced hepatotoxicity are idiosyncratic and occur via an immunological reaction or in response to the presence of hepatotoxic metabolites. With the exception of trovafloxacin and telithromycin hepatotoxicity crude incidence remains globally low but variable (5 patients per 100 000 population). Current data show a genetic association with severe drug-induced liver injury. Antibiotic-induced hepatotoxicity can often be detected early from elevations in serum alanine amino-	· Yes, for the use of Cefuroxime 750 mg and 1500 mg the side effects are described in section 4.8 of the applicants SmPC in the following: 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. Transient rises in serum liver enzymes or bilirubin have been observed which are usually reversible. · Yes, patients at risk are mainly those with previous experience of hepatotoxic reaction to antibiotics,

	transferase (ALT) levels, where these exceed twice the upper limit of normal (ULN). Clinically significant rises in ALT accompanied by jaundice (bilirubin level ≥2 × ULN) suggest a worse prognosis compared with elevated ALT alone, with the combination of hepatocellular injury (ALT >3 × ULN) and jaundice (bilirubin >2 × ULN) being associated with ~10% mortality	the aged or those with impaired hepatic function. Therefore careful evaluation of each patient's medical history before beginning of treatment is highly advisable. · Yes, frequent monitoring of clinical state and appropriate laboratory tests are required in patients with a history of allergic drug reactions or hepatic impairment. Elevated liver enzymes can be detected during routine blood testing. In this case the physician should determine the specific cause by reviewing the medications, signs and symptoms and other tests and procedures.

Missing information

Risk	What is known	Preventability
Use in pregnancy and lactation	Cefuroxime crosses placental barrier and is rapidly excreted into the amniotic fluid. Therapeutic concentrations of cefuroxime were present in umbilical vein serum for up to eight hours after injection. It is therefore well suited for the treatment of certain threatening or established intrauterine infections[1, 2]. Cefuroxime crosses into breast milk. All adverse effects were minor self-limiting and did not necessitate interruption of breast-feeding[3]. Data from Berkovitch et al. 2000[4] suggest that exposure to cefuroxime during the first trimester is probably not associated with an increased risk for malformations or spontaneous abortions. **1:** Bergogne-Berezin E., Pierre J., Rouvillois J.L., Dumez Y.: Placental transfer of cefuroxime in late pregnancy. Drugs Exptl.Clin.Res. 1981; 7(4): 465-469. **2:** Philipson A., Stiernstedt G.: Pharmacokinetics of cefuroxime in pregnancy. Am.J.Obstet.Gynecol. 1982; 142(7): 823-828.	· Yes, for the use of Cefuroxime 750 mg and 1500 mg special warnings are mentioned in the applicants SmPC section 4.6 as following: 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 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. · Yes, careful evaluation of each patient's medical history before beginning of treatment is highly advisable. A risk/benefit analysis of mother and unborn is

	3: Benyamini L., Merlob P., Stahl B., Braunstein R., Bortnik O., Bulkowstein M., Zimmerman D., Berkovitch M.: The safety of amoxicillin/clavulanic acid and cefuroxime during lactation. The Drug Monit. 2005; 27(4): 499-502. **4:** Berkovitch M., Segal-Socher I., Greenberg R., Bulkowshtein M., Arnon J., Merlob P., Or-Noy A.: First trimester exposure to cefuroxime: a prospective cohort study. Br.J.Clin.Pharmacol. 2000; 50: 161-165.	necessary if antibiotics will be given during pregnancy.
Use in hepatic impairment	The pharmacokinetic features of cefuroxime are not affected in cirrhotic patients without ascites. Therefore the antibiotic is particularly suitable for acute infections in hospital and also for cirrhotic patients without ascites without any difference in the dosage.	· Yes, for the use of Cefuroxime 750 mg and 1500 mg a special recommendation is mentioned in the applicants SmPC in section 4.2 as following: Cefuroxime is primarily eliminated by the kidney. In patients with hepatic dysfunction this is not expected to affect the pharmacokinetics of cefuroxime. · Yes, for the use of Cefuroxime 750 mg and 1500 mg information is given in the applicants SmPC in section 4.8 as following: 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. · Yes, careful evaluation of each patient's medical history before beginning of treatment is highly advisable.

Important potential risks

Not applicable – no important potential risks were identified for this product.

Part VI.2.5: Summary of additional risk minimisation measures by safety concern

All medicines have a Summary of Product Characteristics (SmPC) which provides physicians, pharmacists and other health care professionals with details on how to use the medicine, the risks and recommendations for minimising them. An abbreviated version of this in lay language is provided in the form of the package leaflet (PL). The measures in these documents are known as routine risk minimisation measures.

The Summary of Product Characteristics and the Package leaflet for Cefuroxim B. Braun 750 mg and Cefuroxim 1500 mg can be found in the respective EPAR.

This medicine has no additional risk minimisation measures.

Part VI.2.6: Planned post authorisation development plan

Not applicable

Part VI.2.7: Summary of changes to the risk management plan over time

Not applicable – This is the first risk management plan for Cefuroxim B. Braun 750 mg and Cefuroxim B. Braun 1500 mg.