

19.04.2022 SEFUROKSİM İÇEREN ENJEKTABL ÜRÜNLER_EN

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REPUBLIC OF TURKEY MINISTRY OF HEALTH Turkish Medicines and Medical Devices Agency
Number : E-62820468-000-738001 Subject : Re. The Union-Association Decision on Injectable Products Containing Cefuroxime

DOSSIER

Re. : a) Our Union/Association announcement dated 29.09.2010 with the number 65961. b) Our Union/Association announcement dated 16.08.2011 with the number 67395. c) Our Union/Association announcement dated 23.07.2012 with the number 69209.

Our referenced union-association announcements concerning “Drug Products Containing Cefuroxime” shall be cancelled, and you are required to revise the indications section of the SmPC and PIL of injectable products that contain Cefuroxime as follows.

Summary of Product Characteristics of Injectable Products Containing The Active Ingredient Cefuroxime 4.1. Therapeutic Indications DRUG NAME is indicated for the treatment of the following infections caused by susceptible strains of certain microorganisms: 1. Lower respiratory tract infections: Including pneumonia caused by Streptococcus pneumoniae, Haemophilus influenzae (including ampicillin-resistant strains), Klebsiella spp., Staphylococcus aureus (both penicillinase- producing and non-penicillinase producing strains), Streptococcus pyogenes and Escherichia coli. 2. Upper respiratory tract infections: Otitis media caused by Streptococcus pneumoniae, Moraxella catarrhalis and Haemophilus influenzae, sinusitis caused by Staphylococcus aureus. 3. Urinary tract infections: Escherichia coli and Klebsiella spp. 4. Skin and soft tissue infections: Methicillin-susceptible Staphylococcus aureus (both penicillinase-producing and non-penicillinase producing strains), Streptococcus pyogenes, Escherichia coli, Klebsiella spp. and Enterobacter spp. 5. Septicaemia: Except for intramuscular administration (only when the IV form of Cefuroxime is used). Staphylococcus aureus (both penicillinase-producing and non-penicillinase producing strains), Streptococcus pneumoniae, Escherichia coli, Haemophilus influenzae (including ampicillin-resistant strains) and Klebsiella spp. 6. Meningitis: Except for intramuscular administration (only when the IV form of Cefuroxime is used). Streptococcus pneumoniae, Haemophilus influenzae (including ampicillin-resistant strains), Neisseria meningitidis and methicillin-susceptible Staphylococcus aureus (both penicillinase-producing and non- penicillinase producing strains). 7. Gonorrhoea: Uncomplicated and disseminated gonococcal infections caused by Neisseria gonorrhoeae in males and females. 8. Bone and joint infections: Staphylococcus aureus (both penicillinase-producing and non-penicillinase producing strains). Prophylaxis: Preoperative prophylactic use of DRUG NAME decreases the incidence of certain postoperative infections by preventing the growth of pathogenic susceptible bacteria in patients undergoing surgical procedures (e.g. vaginal hysterectomy) classified as clean-contaminated or potentially contaminated. Effective prophylactic use of antibiotics in surgical procedures depend on the timing of medication. DRUG NAME should be administered 1 to 1.5 hours before surgery in order to achieve effective antibiotic concentrations in the wound tissue throughout the procedure. If the surgical procedure is expected to be lengthy, the dose may be repeated during the procedure.

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Normally, prophylactic administration of the drug is not necessary after the surgical procedure. Furthermore, prophylactic administration should be stopped within the 24 hours following the surgical procedure. The perioperative use DRUG NAME is effective during open heart surgery in patients at risk of serious infections in the surgical site. In such patients, it is recommended to extend DRUG NAME treatment up to 48 hours postoperatively. In the event of infection, specimen for culture should be obtained in order to identify relevant microorganism and initiate appropriate antibiotic therapy.

Patient Information Leaflet of Injectable Products Containing The Active Ingredient Cefuroxime 1. What DRUG NAME is and what it is used for DRUG NAME is intended for treatment and protection against bacterial infections. Your doctor has preferred this medicine based on your condition and your illness. It is indicated for the treatment of infections caused by susceptible microorganisms. • Lower respiratory tract infections: Acute and chronic bronchitis (inflammation of bronchi), pneumonia, lung abscess, chest infections after surgery, • Upper respiratory tract infections: Otitis media (middle ear inflammation), sinusitis (inflammation of the air cavities in facial bones), • Urinary tract infections: Acute and chronic pyelonephritis (short- or long-term inflammation of kidneys), inflammation of the bladder, asymptomatic bacteriuria (growth of bacteria without any symptoms), • Skin and soft tissue infections: Cellulitis (skin inflammation that affects the tissues under the skin), erysipelas (a type of skin infection), inflammation of peritoneum, wound infections, • Septicaemia (growth of bacteria by reproducing in blood): Except for administration into muscles (can only be administered into veins), • Meningitis (inflammation of the meninges) Except for administration into muscles (can only be administered into veins), • Gonorrhoea (clap), • Bone and joint infections: This medicine is used to treat diseases such as inflammation of bones and septic arthritis (an inflammatory disease of joints which may be caused by several microorganisms), • Prophylaxis (protection): It may be administered when there is an increased risk in surgeries of the abdomen and the hip as well as orthopaedic, cardiac, lung, oesophagus and vascular surgeries. Sensitivity to Cefuroxime sodium may vary by geographic region and time. You are requested to submit your opinions, recommendations and contributions, if any, in relation to the decision in question to the Clinical Evaluation Unit within 10 (ten) days of the union-association announcement date and not submit any applications concerning “Drug Products Containing Cefuroxime” to the Pharmacological Evaluation Unit and the Regulatory Affairs Unit within the specified time period.

F. Handan ÖZTUNCA, MSc Pharm. Head of Department on behalf of the Agency President

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