Medicines & Healthcare products
Regulatory Agency

# Public Assessment Report

# National Procedure

# Cefuroxime 750 mg powder for solution for injection/infusion
# Cefuroxime 1500 mg powder for solution for injection/infusion

## cefuroxime sodium

## PL 47015/0036 - 0037

## AS KALCEKS

# LAY SUMMARY

## Cefuroxime 750 mg and 1500 mg powder for solution for injection/infusion cefuroxime sodium

This is a summary of the Public Assessment Report (PAR) for Cefuroxime 750 mg and 1500 mg powder for solution for injection/infusion. It explains how these products were assessed and their authorisation recommended, as well as their conditions of use. It is not intended to provide practical advice on how to use these products.

These products will be referred to as Cefuroxime in this lay summary for ease of reading.

These products have been authorised by Medicines and Healthcare products Regulatory Agency (MHRA) for the United Kingdom. These procedures take into account the outcome of decentralised (DC) procedures in European Union Member States (and/or Iceland, Liechtenstein, Norway) on 19 September 2023 (FI/H/1178/001-002/DC). This is known as the MR/DC Reliance Procedure.

These applications were approved under Regulation 51B of the Human Medicines Regulation 2012, as amended (previously Article 10(1) of Directive 2001/83/EC, as amended).

For practical information about using Cefuroxime, patients should read the Patient Information Leaflet (PIL) or contact their doctor or pharmacist.

### What is Cefuroxime and what are these products used for?

These products are generic medicines. This means that these medicines are the same as, and considered interchangeable with, reference medicines already authorised, called Zinacef 750 mg and 1500 mg powder for solution for injection or infusion.

Cefuroxime is used to treat infections of the lungs or bronchi, the urinary tract, skin and soft tissue or the abdomen. Cefuroxime is also used to prevent infections during surgery.

### How does Cefuroxime work?

Cefuroxime is an antibiotic used in adults and children. It works by killing bacteria that cause infections. It belongs to a group of medicines called cephalosporins.

### How is Cefuroxime used?

The pharmaceutical form of these products is powder for solution for injection/infusion and the route of administration is intravenous (into a vein) or intramuscular (into a muscle). It can be given as a drip (intravenous infusion) or as an injection directly into a vein or into a muscle. Cefuroxime is usually given by a doctor or a nurse in a clinical setting.

The patient's doctor may test the type of bacteria causing the patient's infection and monitor whether the bacteria are sensitive to cefuroxime during the treatment.

The correct dose of cefuroxime for the patient will be decided by their doctor and depends on the severity and type of infection, whether the patient is on any other antibiotics; the patient's weight and age and how well their kidneys are working.

For newborn babies (0 to 3 weeks old), for every 1 kg the baby weighs, they'll be given 30 to 100 mg cefuroxime per day divided in two or three doses.

Babies (over 3 weeks) and children are usually given 30 to 100 mg of cefuroxime per day for every 1 kg the baby or child weighs, divided in three or four doses.

For adults and adolescents, usually 750 mg to 1500 mg of cefuroxime is given at either two, three or four times daily.

The maximum dose of Cefuroxime is 6 g per day.

If the patient has kidney problems, their doctor may change the dose.

For further information on how Cefuroxime is used, refer to the PIL and Summaries of Product Characteristics (SmPCs) available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

These medicines can only be obtained with a prescription.

The patients should ask the administering healthcare practitioner if they have any questions concerning their medicine.

**What benefits of Cefuroxime have been shown in studies?**
These cefuroxime products are generic medicines that fulfil criteria meaning that no additional studies are required. Cefuroxime have been considered generic medicines of the reference medicines based on a comparison of their physical and chemical characteristics.

**What are the possible side effects of Cefuroxime?**
For the full list of all side effects reported with these medicines, see Section 4 of the PIL or the SmPCs available on the MHRA website.

If a patient gets any side effects, they should talk to their doctor, pharmacist or nurse. This includes any possible side effects not listed in the product information or the PIL that comes with the medicine. Patients can also report suspected side effects themselves, or a report can be made on their behalf by someone else who cares for them, directly via the Yellow Card scheme at https://yellowcard.mhra.gov.uk or search for 'MHRA Yellow Card' online. By reporting side effects, patients can help provide more information on the safety of this medicine.

**Why were these Cefuroxime products approved?**
MHRA decided that the benefits are greater than the risks and recommended that these medicines can be approved for use.

**What measures are being taken to ensure the safe and effective use of Cefuroxime?**
As for all newly-authorised medicines, a Risk Management Plan (RMP) has been developed for Cefuroxime. The RMP details the important risks of Cefuroxime, how these risks can be minimised, any uncertainties about Cefuroxime (missing information), and how more information will be obtained about the important risks and uncertainties.

There are no safety concerns associated with use of Cefuroxime.

The information included in the SmPC and the PIL is compiled based on the available quality, non-clinical and clinical data, and includes appropriate precautions to be followed by healthcare professionals and patients. Side effects of Cefuroxime are continuously monitored

and reviewed including all reports of suspected side-effects from patients, their carers, and healthcare professionals.

An RMP and a summary of the pharmacovigilance system have been provided with these applications and are satisfactory.

**Other information about Cefuroxime**
Marketing authorisations were granted in the United Kingdom on 5 April 2024.

The full PAR for Cefuroxime follows this summary.

This summary was last updated in May 2024.

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## I. INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the Medicines and Healthcare products Regulatory Agency (MHRA) considered that the applications for Cefuroxime 750 mg and 1500 mg powder for solution for injection/infusion (PL 47015/0036 - 0037) could be approved.

The products are approved for the treatment of the infections listed below in adults and children, including neonates (from birth):

- 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;
- 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.

For more information on the indications and usage of these products, see the Summaries of Product Characteristics available on the MHRA website.

The active ingredient in these products is cefuroxime sodium. 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.

These products have been authorised by MHRA for the United Kingdom. These procedures take into account the outcome of decentralised (DC) procedures in European Union Member States (and/or Iceland, Liechtenstein, Norway) on 19 September 2023 (FI/H/1178/001-002/DC).

For the scientific discussion of the quality, non-clinical and clinical assessment conducted during the DC procedures, please refer to the Reference Member State (RMS) Public Assessment Report, available on the RMS regulatory agency website or on the Heads of Medicines Agencies website.

These applications were approved under Regulation 51B of the Human Medicines Regulation 2012, as amended (previously Article 10(1) of Directive 2001/83/EC, as amended).

The MHRA has been assured that acceptable standards of Good Manufacturing Practice (GMP) are in place for these products at all sites responsible for the manufacture, assembly and batch release of these products.

A Risk Management Plan (RMP) and a summary of the pharmacovigilance system have been provided with these applications and is satisfactory.

Marketing authorisations were granted on 5 April 2024.

## II. PRODUCT INFORMATION

### Summaries of Product Characteristics (SmPCs)

The SmPCs are in line with current guidelines and are satisfactory.

### PATIENT INFORMATION LEAFLET (PIL)

The PIL is in line with current guidelines and is satisfactory.

### LABEL

The labelling is in line with current guidelines and is satisfactory.

## III. QUALITY ASPECTS

MHRA considered that the quality data submitted for these applications is satisfactory. The grant of marketing authorisations was recommended.

## IV. NON-CLINICAL ASPECTS

MHRA considered that the non-clinical data submitted for these applications is satisfactory. The grant of marketing authorisations was recommended.

## V. CLINICAL ASPECTS

MHRA considered that the clinical data submitted for these applications is satisfactory. The grant of marketing authorisations was recommended.

## VI. RISK MANAGEMENT PLAN (RMP)

The applicant has submitted an RMP, in accordance with the requirements of Regulation 182 of The Human Medicines Regulation 2012, as amended. The applicant proposes only routine pharmacovigilance and routine risk minimisation measures for all safety concerns. This is acceptable.

## VII. USER CONSULTATION

A full colour mock-up of the Patient Information Leaflet (PIL) was provided with the application in accordance with legal requirements, including user consultation.

## VIII. OVERALL CONCLUSION, BENEFIT/RISK AND RECOMMENDATION

The quality of the products is acceptable, and no new non-clinical or clinical safety concerns have been identified. The benefit/risk balance is, therefore, considered to be positive.

The Summaries of Product Characteristics (SmPCs), Patient Information Leaflet (PIL) and labelling are satisfactory.

In accordance with legal requirements, the current approved UK versions of the SmPCs and PIL for these products are available on the MHRA website.

## IX. TABLE OF CONTENT OF THE PAR UPDATE

Steps taken after the initial procedure with an influence on the Public Assessment Report (non-safety variations of clinical significance).

Please note that only non-safety variations of clinical significance are recorded below and in the annexes to this PAR. The assessment of safety variations, where significant changes are made, are recorded on the MHRA website or European Medicines Agency (EMA) website. Minor changes to the marketing authorisation are recorded in the current SmPCs and/or PIL available on the MHRA website.

| **Application type** | **Scope** | **Product information affected** | **Date of grant** | **Outcome** | **Assessment report attached Y/N** |
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