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Questions and answers on Zinacef and associated names (cefuroxime sodium, 250 mg, 500mg, 750 mg, 1 g, 1.5 g, 2 g, powder for solution/suspension for injection or infusion)

Outcome of a procedure under Article 30 of Directive 2001/83/EC

On 24 May 2012, the European Medicines Agency completed a review of Zinacef. The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that there is a need to harmonise the prescribing information for Zinacef in the European Union (EU).

What is Zinacef?

Zinacef is an antibiotic used to treat certain bacterial infections, including pneumonia (infection of the lungs), urinary tract infections (infections of the structures that carry urine), soft-tissue infections (infections of tissues just below the skin), infections within the abdomen, as well as to prevent infections during surgery.

The active substance, cefuroxime sodium, belongs to the group 'cephalosporins'. It works by attaching to proteins on the surface of bacteria. This prevents the bacteria from building their cell walls, and eventually kills them.

Zinacef is marketed in all EU Member States (except Germany, Latvia, Slovakia and Spain), as well as Iceland and Norway. It is also available under other trade names: Curocef, Curoxim, Curoxime, Zinnat.

The company that markets these medicines is GlaxoSmithKline.

Why was Zinacef reviewed?

Zinacef is authorised in the EU via national procedures. This has led to divergences across Member States in the way the medicine can be used, as seen in the differences in the summaries of product characteristics (SmPCs), labelling and package leaflets in the countries where the medicine is marketed.

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Zinacef was identified as needing harmonisation by the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh).

On 20 April 2010, the European Commission referred the matter to the CHMP in order to harmonise the marketing authorisations for Zinacef in the EU.

What are the conclusions of the CHMP?

The CHMP, in the light of the data submitted and the scientific discussion within the Committee, was of the opinion that the SmPCs, labelling and package leaflets should be harmonised across the EU.

The areas harmonised include:

4.1 Therapeutic indications

The CHMP agreed that Zinacef should no longer be used to treat severe ear, nose and throat infections as well as bone and joint infections and gonorrhoea (a sexually transmitted infection caused by bacteria called *Neisseria gonorrhoeae*), because not enough clinical data are available to support these indications. The CHMP concluded that Zinacef should be used in adults and children from birth for the following conditions:

- Community-acquired (acquired outside the hospital) pneumonia.
- Acute exacerbations (flares-up) of chronic bronchitis.
- Complicated urinary tract infections, including pyelonephritis (kidney infection).
- 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).

4.2 Posology and method of administration

Having harmonised the indications, the CHMP also harmonised the recommendations on the use of Zinacef in adults and children and in patients with reduced kidney and liver function. Zinacef should be given by injection into a vein over a period of 3 to 5 minutes, by infusion over 30 to 60 minutes, or by deep intramuscular injection, at different doses depending on the condition it is used to treat.

The CHMP also decided that Zinacef should no longer be used in sequential therapy (when switching patients from an injectable to an oral treatment) due to a significant reduction in exposure to the active substance when switching to the oral formulation.

Other changes

The CHMP also harmonised other sections of the SmPC including sections 4.3 (contra-indications) and 4.4 (special warnings and precautions for use).

The amended information to doctors and patients is available here.

The European Commission issued a decision on 10 September 2012.