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Questions and answers on Zinnat and associated names (cefuroxime axetil, 125, 250 and 500 mg tablets and 125, 250 and 500 mg granules for oral suspension)

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

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

What is Zinnat?

Zinnat is an antibiotic used to treat certain infections caused by bacteria, including respiratory tract infections such as tonsillitis and pharyngitis (infections of the throat), urinary tract infections (infections of the structures that carry urine), skin infections, soft-tissue infections (infections of tissues just below the skin) and Lyme disease (bacterial infection transmitted to humans by infected ticks).

The active substance, cefuroxime axetil, 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.

Zinnat is marketed in all EU Member States, as well as Iceland. It is also available under other trade names: Cefuroxima Allen, Cefuroxima Solasma, Elobact, Nivador, Oraxim, Selan, Zinadol, Zipos, Zoref.

The company that markets these medicines is GlaxoSmithKline.

Why was Zinnat reviewed?

Zinnat 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 different EU countries.

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

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

On 20 April 2010, the European Commission referred the matter to the CHMP in order to harmonise the marketing authorisations for Zinnat 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 Zinnat should no longer be used to treat community acquired pneumonia (infection of the lungs acquired outside the hospital) 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 Zinnat should be used in adults and children from three months of age for the following conditions:

- Acute streptococcal tonsillitis and pharyngitis (infections of the tonsils and throat).
- Acute bacterial sinusitis (infection of the sinuses).
- Acute otitis media (infection of the middle ear).
- Acute exacerbations (flares-up) of chronic bronchitis.
- Cystitis (infection of the bladder).
- Pyelonephritis (kidney infection).
- Uncomplicated skin and soft tissue infections.
- Treatment of early Lyme disease.

4.2 Posology and method of administration

Having harmonised the indications, the CHMP also harmonised the recommendations on the use of Zinnat in adults and children and in patients with reduced kidney and liver function. Zinnat should be used twice a day at different doses depending on the condition it is used to treat.

The CHMP also decided that Zinnat 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 23 August 2012.