European Medicines Agency
Evaluation of Medicines for Human Use

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PUBLIC STATEMENT ON

Levviax
(Telithromycin)

WITHDRAWAL OF THE MARKETING AUTHORISATION IN THE EUROPEAN UNION

On 9 July 2001 the European Commission issued a marketing authorisation valid throughout the European Union for the medicinal product Levviax 400 mg film coated tablets.

Levviax is indicated for the treatment of the following infections:
In patients of 18 years and older:
• Community-acquired pneumonia, mild or moderate.
• When treating infections caused by known or suspected beta-lactam and/or macrolide resistant strains (according to history of patients or national and/or regional resistance data) covered by the antibacterial spectrum of telithromycin:
- Acute exacerbation of chronic bronchitis,
- Acute sinusitis
In patients of 12 years and older:
•Tonsillitis/pharyngitis caused by S*treptococcus pyogenes,* as an alternative when beta lactam antibiotics are not appropriate in countries/regions with a significant prevalence of macrolide resistant S. pyogenes, when mediated by ermTR or mefA (see sections 4.4 and 5.1).
intended for the treatment of infections due to bacteria in adults and adolescents of 12 years and older.

The marketing authorisation holder (MAH) responsible for Levviax is Aventis Pharma S.A. On 13 November 2007, the European Commission was notified by the MAH of its decision to voluntarily withdraw the marketing authorisation for Levviax for commercial reasons.

Levviax was never marketed in the European Union. Ketek is an identical product available in the European Union.

On 18 December 2007 the European Commission issued a decision to withdraw the marketing authorisation for Levviax. Pursuant to this decision the European Public Assessment Report for Levviax will be updated to reflect that the marketing authorisation is no longer valid.

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