European Medicines Agency

EMEA/H/C/0355

COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

LEVVIAX

International Nonproprietary Name (INN): **Telithromycin**

Abstract

Active substance:	Telithromycin
Pharmaco-therapeutic group (ATC Code):	Antibacterial for systemic use JO1
Currently approved therapeutic indication(s):	When prescribing Levviax, consideration should be given to official guidance on the appropriate use of antibacterial agents. Levviax is indicated for the treatment of the following infections: *In patients of 18 years and older:* - Community-acquired pneumonia, mild or moderate, - Acute exacerbation of chronic bronchitis, - Acute sinusitis, - Tonsillitis/pharyngitis caused by Group A *beta streptococci,* as an alternative when beta lactam antibiotics are not appropriate**.** *In patients of 12 to 18 years old:* Tonsillitis/pharyngitis caused by Group A *beta streptococci*, as an alternative when beta lactam antibiotics are not appropriate
Authorised presentations:	See the Module ”All authorised presentations”
Marketing Authorisation Holder:	Aventis Pharma S.A. 20 avenue Raymond Aron F-92160 Antony France
Date of issue of Marketing Authorisation valid throughout the European Union:	9 July 2001
Orphan medicinal product designation date:	Not applicable

The active substance of Levviax is telithromycin, an antibacterial medicinal product which is a novel semi-synthetic antibacterial agent belonging to a new family of antibiotics, the ketolides, closely related to the well-known macrolide antibiotics. The pharmacological action of telithromycin involves inhibition of bacterial protein synthesis and is similar to that of macrolides, but

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differences on the molecular level may exist. Telithromycin interacts with the translation at the 23S ribosomal RNA level and some data also indicate that assembly of the 30S subunit may be impaired.

Clinical trials, in general, support similar efficacy of telithromycin and comparators in the indications investigated (CAP not clinically serious enough to warrant parenteral therapy but efficacy has been demonstrated in a limited number of patients with risk factors such as pneumococcal bacteraemia or age higher than 65 years, AECB, sinusitis, and pharyngotonsillitis caused by *S. pyogenes)*.

The initial approval was based on studies, which showed that the potential benefits with telithromycin particularly relate to its use in the treatment of infections caused by penicillin and/or erythromycin resistant *S. pneumoniae*. However, clinical experience is still rather limited in the treatment of these infections, and therefore telithromycin should be used with caution until further experience of emergence of resistance has been gained, especially in areas with a high prevalence of resistant pneumococci. The most common side effects are, as for macrolides, mainly reported from the digestive and nervous systems, with diarrhoea, nausea, headache and dizziness. Adverse events assessed as possibly related to study treatment were reported for 35.8% of the telithromycin patients, versus 28.3% of the comparators. The frequency and severity of increased hepatic enzyme activity and liver disease appear similar to clarithromycin but justify close post-marketing surveillance, as does the potential prolongation of the QT-interval

The CHMP, on the basis of quality, safety and efficacy data submitted, considers that the benefit risk ratio for Levviax is favourable in the approved indication

For detailed conditions for the use of this product, scientific information or procedural aspects please refer to the relevant modules.