



European Medicines Agency
Press office

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PRESS RELEASE

European Medicines Agency recommends restricted use and strengthened warnings for Ketek

The European Medicines Agency (EMA) has recommended restrictions on the use of Ketek (telithromycin) in three of its four approved indications. For the treatment of bronchitis, sinusitis and tonsillitis/pharyngitis, Ketek should only be used for infections caused by bacterial strains that are suspected or proven to be resistant to or cannot be treated with macrolide or beta-lactam antibiotics.

No such restrictions are recommended for the remaining indication, the treatment of community-acquired pneumonia.

The Agency's Committee for Medicinal Products for Human Use (CHMP) also recommended the contraindication of the use of Ketek in patients with myasthenia gravis and strengthened warnings on transient loss of consciousness and effects on vision.

The CHMP has been carrying out a comprehensive review of the safety and effectiveness of Ketek since January 2006, following reports of severe liver injuries in patients taking telithromycin. As part of this review several updates relating to the safety of Ketek were made to the Product Information during 2006. These included strengthening the warnings on serious liver reactions and contraindicating the use of the medicine in patients with a previous history of serious liver disorders. In January 2007, the Committee requested updated information from the marketing authorisation holder for Ketek, to allow a comprehensive assessment of the benefits and risks in each of the medicine's approved indications.

Finalising the review at its 19-22 March 2007 meeting, the Committee concluded that the effectiveness of Ketek has been demonstrated in the approved indications. However, its use is associated with a greater risk of certain side effects, some of which may be serious. These include a worsening of myasthenia gravis (which can be life-threatening), transient loss of consciousness, and temporary visual disturbances. Severe problems with the liver have been reported rarely, but do not occur more frequently than with other relevant antibiotic medicines.

The Committee concluded that the benefits of Ketek continue to outweigh its risks in the treatment for bronchitis, sinusitis and tonsillitis/pharyngitis, if used in accordance with the updated product information.

Prescribers are advised to consider the official guidance on the appropriate use of the antibiotics and the local prevalence of resistance.

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NOTES

1. More information about the recommendations for Ketek is available in a separate [question and answer document](#).
2. The European Commission is currently conducting the procedures laid down in Community legislation with a view to issuing a decision to update the product information for Ketek.
3. The updated product information, for which the Commission decision is pending, is available [here](#).

4. In the European Union, telithromycin is authorised as Ketek and Levviax. The marketing authorisation holder is Aventis Pharma S.A. It is marketed only as Ketek. The European public assessment report for Ketek is published on the EMEA website and can be found [here](#).
5. Ketek is marketed in the European Union/European Economic Area in Austria, Belgium, Cyprus, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Malta, Norway, Portugal, Slovenia, Spain, Sweden and the United Kingdom.
6. The EMEA's statement on the safety of Ketek from January 2006 can be found [here](#).
7. This press release, together with other information about the work of the EMEA, may be found on the EMEA website: <http://www.emea.europa.eu>.

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