FDA News

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FDA Announces Label and Indication Changes for the Antibiotic Ketek

The Food and Drug Administration (FDA) today announced revisions to the labeling for the antibiotic Ketek (telithromycin) designed to improve the safe use of Ketek by patients. The changes include the removal of two of the three previously approved indications -- acute bacterial sinusitis and acute bacterial exacerbations of chronic bronchitis -- from the drug's label. The agency has determined that the balance of benefits and risks no longer support approval of the drug for these indications. Ketek will remain on the market for the treatment of community acquired pneumonia of mild to moderate severity (acquired outside of hospitals or long-term care facilities).

In addition, the agency has worked with the company, Sanofi Aventis, to update the product labeling with a "boxed warning," FDA's strongest form of warning. The warning states that Ketek is contraindicated (should not be used) in patients with myasthenia gravis, a disease that causes muscle weakness.

FDA also worked with the manufacturer to develop a Patient Medication Guide -- that informs patients about the risk of the drug and how to use it safely. The Medication Guide (an FDA-approved patient information sheet) will be provided to patients with each prescription.

"Today's action is the result of comprehensive scientific analysis and thoughtful public discussion of the data available for Ketek, and includes important changes in the labeling designed to improve the safe use of Ketek by patients and give healthcare providers the most up-to-date prescribing information," said Steven Galson, M.D., Director, Center for Drug Evaluation and Research.

Other labeling changes included in today's action are a strengthened warning section regarding specific drug-related adverse events including visual disturbances and loss of consciousness. Warnings for hepatic toxicity (rare but severe symptoms of liver disease) were strengthened in June 2006.

The joint advisory committee, which met on December 14 and 15, 2006, advised that the available data including data acquired since the initial approval of Ketek support a conclusion that the benefits of Ketek outweigh the risks in patients with community acquired pneumonia, but not for patients with acute bacterial sinusitis or acute bacterial exacerbation of chronic bronchitis. They also recommended a boxed warning as well as Medication Guide for the drug. The joint panel consisted of FDA's Anti-Infective Drugs and Drug Safety and Risk Management Advisory committees.

The antibiotic Ketek was originally approved in 2004 and is manufactured by Sanofi Aventis.

For additional information, visit: http://www.fda.gov/cder/drug/infopage/telithromycin/default.htm

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