



Therapeutic Class ReviewSM

Anti-infectives - telithromycin (Ketek[®]) tablets

May 2005

New Product for Review
telithromycin (Ketek) [Aventis]

Dossier Provided by Manufacturer: yes
Quality of Dossier: 3

Low quality (dossier w/missing components)

1. Medium quality (all components, except pharmacoeconomic model)
2. High quality (all components, well done)

Executive Summary

- Telithromycin (Ketek) is an antibiotic used to treat upper respiratory tract infections.
- Greater in-vitro activity for telithromycin (Ketek) has not been shown to correlate with greater microbiological cure in clinical trials.
- There is no evidence that telithromycin (Ketek) provides a superior benefit in treating upper respiratory tract infections compared to other antibiotics.
- Telithromycin (Ketek) has at least similar efficacy as other antibiotics [moxifloxacin (Avelox), clarithromycin (Biaxin), amoxicillin/clavulanic acid (Augmentin), and cefuroxime (Ceftin)] in treating acute bacterial sinusitis (ABS), acute bacterial exacerbation of chronic bronchitis (ABECB), and community-acquired pneumonia (CAP).
- Ketek has an unfavorable risk to benefit profile relative to other comparator antibiotics.
- There is a higher rate of visual adverse events with telithromycin (Ketek) versus comparator-antibiotics.
 - ⇒ Vision impairment may be severe and occurs more often in females less than 40 years old
 - ⇒ Telithromycin (Ketek) may significantly worsen symptoms in patients with myasthenia gravis.
- The FDA concluded that the frequency and severity of hepatic and cardiac toxicity with telithromycin (Ketek) is consistent with antibiotics in the macrolide class.
- Clinically significant drug-drug interactions with telithromycin (Ketek) and chronic medications increase risks for adverse events with its use:

Decision

Maintain telithromycin (Ketek) as non-preferred/non-formulary because telithromycin (Ketek) offers no clinical advantage over other formulary agents in eradicating pathogens indicated in ABECB, ABS and CAP, and is associated with ocular adverse effects.

I. Products

Drug Product	Date of FDA Approval	FDA Approved Indication(s)	Dose Route	Potential Off-Label Use(s)
telithromycin (Ketek) 400 mg tablets	April 2004	<ul style="list-style-type: none"> ▪ Acute bacterial exacerbation of chronic bronchitis (ABECB) due to <i>Streptococcus pneumoniae</i>, <i>Haemophilus influenzae</i>, or <i>Moraxella catarrhalis</i>. ▪ Acute bacterial sinusitis (ABS) due to <i>S. pneumoniae</i>, <i>H. influenzae</i>, <i>M. catarrhalis</i>, or <i>S. aureus</i>. ▪ Mild to moderate Community-acquired pneumonia (CAP) due to <i>S. pneumoniae</i>, (including multi-drug resistant isolates), <i>H. influenzae</i>, <i>M. catarrhalis</i>, <i>C. pneumoniae</i>, or <i>M. pneumoniae</i>. 	Oral	Pharyngitis/ tonsillitis ^[1] Tonsillo-pharyngitis ^[2]
azithromycin (Zithromax)	June 1996	<ul style="list-style-type: none"> ▪ ABECE due to <i>H. influenzae</i>, <i>M. catarrhalis</i>, or <i>S. pneumoniae</i>. ▪ Mild CAP due to <i>S. pneumoniae</i> or <i>H. influenzae</i>. ▪ Streptococcal pharyngitis/ tonsillitis due to <i>S. pyogenes</i> 	Oral	
clarithromycin (Biaxin)	October 1991	<ul style="list-style-type: none"> ▪ Streptococcal pharyngitis/ tonsillitis due to <i>S. pyogenes</i> ▪ Acute maxillary sinusitis due to <i>H. influenzae</i>, <i>M. catarrhalis</i>, or <i>S. pneumoniae</i> ▪ ABECE due to <i>H. influenzae</i>, <i>M. catarrhalis</i>, or <i>S. pneumoniae</i>. ▪ Pneumonia due to <i>H. influenzae</i>, <i>M. pneumoniae</i>, <i>S. pneumoniae</i>, or <i>C. pneumoniae</i> (TWAR). 	Oral	
amoxicillin/ clavulanic acid (Augmentin)	July 1985	<ul style="list-style-type: none"> ▪ Sinusitis caused by β-lactamase-producing strains of <i>H. influenzae</i> and <i>M. catarrhalis</i>. ▪ Lower Respiratory Tract Infections caused by β-lactamase-producing strains of <i>H. influenzae</i> and <i>M. catarrhalis</i>. ▪ Otitis Media caused by β-lactamase-producing strains 	Oral	
cefuroxime (Ceftin)	December 1987	<ul style="list-style-type: none"> ▪ Streptococcal pharyngitis/ tonsillitis due to <i>S. pyogenes</i> ▪ Acute maxillary sinusitis (AMS) due to <i>H. influenzae</i>, <i>M. catarrhalis</i>, or <i>S. pneumoniae</i> ▪ ABECE due to <i>H. influenzae</i>, <i>M. catarrhalis</i>, or <i>S. pneumoniae</i>. ▪ See package insert for other indications not related to upper or lower respiratory tract infection. 	Oral	

*AWP (average wholesale price) based on First Data Bank as of November 15, 2004.

Products (continued)

Drug Product	Date of FDA Approval	FDA Approved Indication(s)	Dose Route	Potential Off-Label Use(s)
moxifloxacin (Avelox)	December 1999	<ul style="list-style-type: none"> ▪ ABS caused by <i>S. pneumoniae</i>, <i>H. influenzae</i>, or <i>M. catarrhalis</i>. ▪ ABECB caused by <i>S. pneumoniae</i>, <i>H. influenzae</i>, <i>K. pneumoniae</i>, <i>H. parainfluenzae</i>, <i>S. aureus</i>, and <i>M. catarrhalis</i>. ▪ CAP caused by <i>S. pneumoniae</i> (including penicillin resistant strains), <i>H. influenzae</i>, <i>M. catarrhalis</i>, <i>S. aureus</i>, <i>K. pneumoniae</i>, <i>M. pneumoniae</i>, or <i>C. pneumoniae</i>. ▪ See package insert for other indications not related to upper or lower respiratory tract infection. 	Oral	
gemifloxacin (Factive)	April 2003	<ul style="list-style-type: none"> ▪ ABECB caused by <i>S. pneumoniae</i>, <i>H. influenzae</i>, <i>H. parainfluenzae</i>, or <i>M. catarrhalis</i>. ▪ CAP (of mild to moderate severity) caused by <i>S. pneumoniae</i> (including multi-drug resistant strains), <i>H. influenzae</i>, <i>M. catarrhalis</i>, <i>M. pneumoniae</i>, <i>C. pneumoniae</i>, or <i>K. pneumoniae</i>. 	Oral	
levofloxacin (Levaquin)	December 1996	<ul style="list-style-type: none"> ▪ AMS due to <i>S. pneumoniae</i>, <i>H. influenzae</i>, or <i>M. catarrhalis</i>. ▪ ABECB caused by <i>S. pneumoniae</i>, <i>H. influenzae</i>, <i>K. pneumoniae</i>, <i>H. parainfluenzae</i>, <i>S. aureus</i>, and <i>M. catarrhalis</i>. ▪ CAP caused by <i>S. pneumoniae</i> (including penicillin resistant strains), <i>H. influenzae</i>, <i>M. catarrhalis</i>, <i>S. aureus</i>, <i>K. pneumoniae</i>, <i>M. pneumoniae</i>, or <i>C. pneumoniae</i>. ▪ See package insert for other indications not related to upper or lower respiratory tract infection. 	Oral	
gatifloxacin (Tequin)	December 1999	<ul style="list-style-type: none"> ▪ ABS caused by <i>S. pneumoniae</i>, <i>H. influenzae</i>, or <i>M. catarrhalis</i>. ▪ ABECB caused by <i>S. pneumoniae</i>, <i>H. influenzae</i>, <i>K. pneumoniae</i>, <i>H. parainfluenzae</i>, <i>S. aureus</i>, and <i>M. catarrhalis</i>. ▪ CAP caused by <i>S. pneumoniae</i> (including penicillin resistant strains), <i>H. influenzae</i>, <i>M. catarrhalis</i>, <i>S. aureus</i>, <i>K. pneumoniae</i>, <i>M. pneumoniae</i>, or <i>C. pneumoniae</i>. ▪ See package insert for other indications not related to upper or lower respiratory tract infection. 	Oral	

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