

July 2004

# Update Information



## NEW DRUG TERMS

	<u>NUMBER</u>
AZD-3582 .....	28080536
MARIGOLD .....	92510186
SECRETIN, HUMAN .....	36610008

## CONTINUING EDUCATION ARTICLES

**Article Number 516847:** Cada DJ, Levien T, Baker DE. Intravenous N-Acetylcysteine. *Hosp Pharm* 2004, 39:564-570. (0.15 CEU)

**Article Number 516479:** Cada DJ, Levien T, Baker DE. Botulism Immune Globulin Intravenous. *Hosp Pharm* 2004, 39:470-477. (0.15 CEU)

## **FDA APPROVAL PACKAGE**

**Article Number 516211-516221:** Anonymous. Annotated Table of Contents. **Pemetrexed for Injection, Alimta.** Summary Basis of Approval Equivalent. *FDA Approval Package* 2004.

## IDIS COVERAGE OF NEWLY APPROVED DRUGS

### **Human Secretin Injection, Human Secretin®, Chirhoclin**

**FDA Approval Indication** April 9, 2004, priority review for previous orphan drug  
**Uses:**  
 Stimulation of pancreatic secretions to aid in the diagnosis of pancreatic exocrine dysfunction.  
 Stimulation of gastrin secretion to aid in the diagnosis of gastrinoma.  
 Stimulation of pancreatic secretions to facilitate the identification of the ampulla of Vater and accessory papilla during endoscopic retrograde cholangiopancreatography (ERCP).

**IDIS Database** 1 Randomized Controlled Clinical Trial  
1 Observational Study with Control  
1 Case Report

**IDIS Drug Term** SECRETIN, HUMAN 36610008  
**IDIS Disease Term** DIAG TEST-DIGEST/BMR 89.39  
 DISEASE, PANCREATIC NEC 577.  
 NEOP, NOS-DIGESTIVE SYSTEM 239.0

(continued)

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**IDIS COVERAGE OF NEWLY APPROVED DRUGS - Continued**

**Telithromycin Tablet, Ketek®, Aventis Pharms**

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**FDA Approval** April 1, 2004, standard review

**Indication** Use in adults to treat:  
Acute bacterial exacerbation of chronic bronchitis,  
due to *Streptococcus pneumoniae*, *Haemophilus influenzae*, or *Moraxella*  
*catarrhalis*.

Acute bacterial sinusitis due to *Streptococcus pneumoniae*,  
*Haemophilus influenzae*, *Moraxella catarrhalis*, or *Staphylococcus aureus*.

Community-acquired pneumonia (of mild to moderate severity) due to  
*Streptococcus pneumoniae*, *Haemophilus influenzae*, *Moraxella catarrhalis*,  
*Chlamydophila pneumoniae*, or *Mycoplasma pneumoniae*.

**IDIS Database** 13 Randomized Controlled Clinical Trials  
4 Observational Studies, No Control  
16 Reviews  
3 Case reports

**IDIS Drug Term** TELITHROMYCIN 8121223  
**IDIS Disease Terms** BRONCHITIS, ACUTE 466.0  
SINUSITIS, ACUTE 461.  
PNEUMONIA, BACTERIAL NEC 482.