

Report on New Patented Drugs - Ketek

Under its transparency initiative, the PMPRB publishes the results of the reviews of new patented drugs by Board Staff, for purposes of applying the PMPRB's *Excessive Price Guidelines* (Guidelines) for all new active substances introduced after January 1, 2002.

Brand Name: Ketek

Generic Name: (*telithromycin*)

DIN: 02247520 400 mg tablet

Patentee: sanofi-aventis Canada Inc. (previously Aventis Pharma Inc.)

Indication - as per product monograph:

For the treatment of the following infections when caused by susceptible strains of the designated pathogens in the specific conditions listed below. For the treatment of patients 18 years old and older, except in tonsillitis/pharyngitis in which Ketek is indicated for the treatment of patients 13 years of age and older.

- Community-acquired pneumonia (mild to moderate) due to *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Chlamydophila (chlamydia) pneumoniae*, *Mycoplasma pneumoniae*
- Acute bacterial exacerbation of chronic bronchitis due to *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Moraxella catarrhalis*
- Tonsillitis/pharyngitis due to *Streptococcus pyrogenes* (group A-B hemolytic streptococci), as an alternative when B-lactam antibiotics are not appropriate.

Date of Issuance of First Patent(s) Pertaining to the Medicine: January 22, 2002

Notice of Compliance: May 28, 2003

Date of First Sale: May 29, 2003

ATC Class: J01FA15
Antiinfectives for Systemic Use, Antibacterials for Systemic Use, Macrolides, Lincosamides and Streptogramins, Macrolides

APPLICATION OF THE GUIDELINES

Summary

The introductory price of Ketek 400 mg tablet was found to be within the Guidelines because the cost of therapy did not exceed the cost of therapy of existing drugs in the therapeutic class comparison and the price did not exceed the prices in the other comparator countries where Ketek was sold.

Scientific Review

The Guidelines provide that new DINs with multiple approved indications will be categorized based on the approved indication for which the medicine offers the greatest therapeutic advantage in relation to alternative therapies for the same indication in a significant population. Where there is no apparent single approved indication for which the medicine offers the greatest therapeutic advantage, the approved indication representing, potentially, the greatest proportion of sales will be the basis for categorization and selection of comparable medicines.

The PMPRB's Human Drug Advisory Panel (HDAP) recommended that the primary indication for Ketek is the treatment of acute bacterial exacerbations of chronic bronchitis (AECB) and that Ketek be reviewed as a category 3 new medicine (provides moderate, little or no therapeutic advantage over comparable medicines).

The Therapeutic Class Comparison (TCC) test of the Guidelines provides that the price of a category 3 new drug product cannot exceed the prices of other drugs that treat the same disease or condition. Comparators are generally selected from among existing drug products in the same 4th level of the Anatomical Therapeutic Chemical (ATC) System that are clinically equivalent in addressing the approved indication. See the PMPRB's *Compendium of Guidelines, Policies and Procedures* for a more complete description of the Guidelines and the policies on TCCs.

The HDAP identified Eryc (*erythromycine*), Zithromax (*azithromycin*) and Biaxin/Biaxin XL (*clarithromycin*) as appropriate comparators, given they are within the same 4th level ATC classification and are used in the management of AECB.

The Guidelines provide that the dosage recommended for comparison purposes will normally not be higher than the maximum of the usual recommended dosage. The recommended comparable dosage regimens for Ketek and the comparators are based on their respective product monographs, clinical literature, current practice guidelines and clinical practice.

Price Review

Under the Guidelines, the introductory price of a new category 3 drug product will be presumed to be excessive if it exceeds the prices of all of the comparable drug products in the TCC test, or if it exceeds the prices of the same medicine in the seven countries listed in the *Patented Medicines Regulations*. The price of Ketek was within the Guidelines as the cost per treatment did not exceed the cost per treatment with the comparator medicines.

Introductory Period (May to June 2003)			
Name	Strength	Dosage Regimen	Cost per Treatment
Ketek (telithromycin)	400 mg/tab	10 tablets	\$31.0500¹
Eryc (<i>erythromycin</i>)	250 mg/cap	20 capsules	\$4.2400 ²
Eryc (<i>erythromycin</i>)	333 mg/cap	15 capsules	\$7.1730 ³
Zithromax (<i>azithromycine</i>)	250 mg/tab	6 tablets	\$29.5998 ³
Biaxin XL (<i>clarithromycine</i>)	500 mg/tab	14 tablets	\$35.2016 ³
Biaxin (<i>clarithromycin</i>)	500 mg/tab	14 tablets	\$41.4120 ⁴

1. Association québécoise des pharmaciens propriétaires (AQPP), October 2005
2. PPS Pharma, January 2003
3. Ontario Drug Benefit Formulary, January 2003
4. Régie de l'assurance maladie du Québec, February 2003

At introduction, Ketek 400 mg tablet was sold in four of the seven countries listed in the Regulations, namely France, Germany, Italy, and Sweden. In compliance with the Guidelines, the prices in Canada did not exceed the range of prices in those countries; the price of Ketek in Canada was the lowest of those countries, below the median international price.

Where comparators and dosage regimens are referred to in the Summary Reports, they have been selected by the PMPRB Staff and the HDAP for the purpose of carrying out the PMPRB's regulatory mandate, which is to review the prices of patented medicines sold in Canada to ensure that such prices are not excessive. The publication of these reports is also part of the PMPRB's commitment to make its price review process more transparent.

The information contained in the PMPRB's Summary Reports should not be relied upon for any purpose other than its stated purpose and is not to be interpreted as an endorsement, recommendation or approval of any drug nor is it intended to be relied upon as a substitute for seeking appropriate advice from a qualified health care practitioner.

References – Ketek

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