

Report on New Patented Drugs – Pariet

Brand Name:	Pariet	
Generic Name:	rabeprazole sodium	
DIN:	02243796	10 mg/tablet
	02243797	20 mg/tablet
Patentee:	Janssen-Ortho Inc.	
Indications (as per product monograph):	For the treatment of conditions where a reduction of gastric secretion is required, such as: <ol style="list-style-type: none">1. Symptomatic relief and healing of erosive or ulcerative gastroesophageal reflux disease (GERD)2. Long-term maintenance of healing of erosive or ulcerative gastroesophageal reflux disease (GERD)3. Symptomatic relief and healing of duodenal ulcers4. Symptomatic relief and healing of gastric ulcers5. Long-term treatment of pathological hypersecretory conditions, including Zollinger-Ellison syndrome.	
Notice of Compliance:	May 7, 2001	
Date of First Sale:	July 3, 2002	
ATC Class:	A02BC04 <i>Drugs for Peptic Ulcer and Gastroesophageal Reflux Disease (GERD), Proton Pump Inhibitors</i>	

Application of the Guidelines

Summary:

The introductory prices of Pariet were 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 prices did not exceed the range of prices in other comparator countries where Pariet was sold.

Scientific Review:

Pariet is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) reviewed it 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.

Pariet is the fifth entry in the 4th level ATC. Members of the 4th level ATC comparators include Losec (omeprazole), Pantoloc (pantoprazole), Prevacid (lansoprazole) and Nexium (esomeprazole). All of these agents share similar indications and clinical use. The HDAP recommended that they all be included in the TCC for Pariet.

The PMPRB's 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 Pariet and the comparators are based on their respective product monographs and supported by clinical literature. See the table on page 8.

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 price 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*.

Under our transparency initiative, we publish the results of the reviews of new patented drugs by Board Staff, for purposes of applying the PMPRB's Price Guidelines, for all new active substances (NASs) introduced after January 1, 2002. The Reports are posted on our website as they become available. You can access the Reports on NASs under Patented Medicines; Reports on New Patented Drugs for Human Use. Reports on patented drugs for veterinary use are also accessible under Reports on New Patented Drugs for Veterinary Use.

As shown in the following table, the prices of Pariet were within the Guidelines relative to the TCC test, as they did not exceed the prices of the other drugs in the therapeutic class.

Name	Strength	Dosage Regimen/day	Unit Price	Cost Per Day
Pariet	10 mg/tab	2 tablets	\$0.65/tab ¹	\$1.30
Pantoloc	20 mg/tab	1 tablet	\$1.79/tab ²	\$1.79
Losec	20 mg/tab	1 tablet	\$2.20/tab ³	\$2.20
Prevacid	15 mg/cap	1 capsule	\$2.00/cap ³	\$2.00
Nexium	20 mg/tab	1 tablet	\$2.10/tab ¹	\$2.10
Pariet	20 mg/tab	1 tablet	\$1.89/tab ⁴	\$1.89
Pantoloc	20 mg/tab	1 tablet	\$1.79/tab ²	\$1.79
Losec	20 mg/tab	1 tablet	\$2.20/tab ³	\$2.20
Prevacid	15 mg/cap	1 capsule	\$2.00/cap ³	\$2.00
Nexium	20 mg/tab	1 tablet	\$2.10/tab ¹	\$2.10

- 1 Liste de médicaments du Québec, June 2003
- 2 Medis, 2002
- 3 Ontario Drug Benefit Formulary, 2002
- 4 Price filed by Janssen-Ortho Inc.

In 2002, Pariet 10 mg/tablet was also being sold in France, Germany, Italy, Sweden, and the United Kingdom, and Pariet 20 mg/tablet was being sold in France, Germany, Italy, Sweden, the United Kingdom and the United States. In compliance with the Guidelines, the price in Canada did not exceed the range of prices in those countries. The price in Canada for Pariet 10 mg/tablet was the lowest, and the price in Canada for Pariet 20mg/tablet was third highest, above the median international price.

Evidence/ References:

The references are available on the PMPRB website, under Publications, Patented Medicines; Reports on New Patented Drugs for Human Use; Pariet.

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. ■