

March 2006

Report on New Patented Drugs - Keppra

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: Keppra

Generic Name: (*levetiracetam*)

DIN:	2247027	Tablet	250 mg
	2247028	Tablet	500 mg
	2247029	Tablet	750 mg

Patentee: Lundbeck Canada Inc.

Indication - as per product monograph:

As adjunctive therapy in the management of patients with epilepsy who are not satisfactorily controlled by conventional therapy.

Date of Issuance of First Patent(s) Pertaining to the Medicine: April 12, 1988

Notice of Compliance: March 6, 2003

Date of First Sale: July 18, 2003

ATC Class: N03AX14
Nervous Systems, Antiepileptics, Antiepileptics, Other antiepileptics

APPLICATION OF THE GUIDELINES

Summary

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

Scientific Review

Keppra is a new active substance and the 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. 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 recommended Lamictal (*lamotrigine*), Topamax (*topiramate*) and Neurontin (*gabapentin*) as the appropriate comparators for purposes of a TCC test. These 4th level ATC comparators share the same indication as Keppra.

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 Keppra and the comparators are based on respective product monographs and supported by clinical literature.

Due to difficulties in establishing comparative doses for the 250 mg and 500 mg strength tablets, the HDAP recommended that these two strengths be compared on a milligram per milligram basis to Keppra 750 mg tablet.

Price Review

Under the Guidelines, the introductory price for a new category 3 drug product will be presumed to be excessive if it exceeds the prices of all of the comparable drug products based on the TCC test, and if it exceeds the prices of the same medicine in the seven countries listed in the *Patented Medicines Regulations*.

Introductory Period (July to December 2003)

Name	Strength	Dosage Regimen	Unit Price	Cost per Day
Keppra	750 mg tablet	2 tablets	2.5900 ¹	5.1800
Lamictal	150 mg tablet +	2 tablets +	1.9890 ² +	3.9780 +
	100 mg tablet	2 tablets	<u>1.3260</u> ² 3.3150	<u>2.6520</u> 6.6300
Neurontin	400 mg capsule +	3 capsules +	1.1595 ² +	3.4785 +
	800 mg tablet	3 tablets	<u>2.3190</u> ² 3.4785	<u>6.9570</u> 10.4355
Topamax	200 mg tablet	2 tablets	3.1500 ²	6.3000

Source: ¹PPS Pharma Publication, January 2004

²Liste de médicaments du Québec, October 2003

A Reasonable Relationship test was conducted for Keppra 250 mg tablet and 500 mg tablet. The prices of Keppra 250 mg tablet (\$1.4900) and 500 mg tablet (\$1.8200) were within the Guidelines. These prices appear in the PPS Pharma Publication, January 2004.

In 2003, Keppra 250 mg tablet was sold in France, Germany, Sweden, Switzerland, the United Kingdom and the United States (Canadian price was second highest, above the median); Keppra 500 mg tablet was sold in France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States (Canadian price was sixth lowest, below the median); and Keppra 750 mg tablet was only sold in the United States. In compliance with the Guidelines, the prices in Canada did not exceed the range of prices in those countries.

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 - Keppra

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