

Report on New Patented Drugs – Enablex

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: Enablex

Generic Name: (*darifenacin hydrobromide*)

DIN: 02273217 (7.5 mg/tablet)
02273225 (15 mg/tablet)

Patentee: Novartis Pharmaceuticals Canada Inc.

Indication - as per product monograph:

For the treatment of overactive bladder

Date of Issuance of First Patent(s)

Pertaining to the Medicine: November 12, 1996

Notice of Compliance: November 14, 2005

Date of First Sale: April 6, 2006 (7.5 mg/tablet)
April 11, 2006 (15 mg/tablet)

ATC Class: G04BD10
*Genito Urinary System and Sex Hormones; Urologicals;
Other Urologicals, incl. Antispasmodics; Urinary
Antispasmodics*

APPLICATION OF THE GUIDELINES

Summary

The introductory prices of Enablex 7.5 mg/tablet and 15 mg/tablet were found to be within the Guidelines because the daily cost of therapy did not exceed the daily cost of therapy of existing drugs in the therapeutic class comparison and the price did not exceed the range of prices in the other comparator countries listed in the *Patented Medicines Regulations, 1994* (Regulations) where Enablex 7.5 mg and 15 mg/tablets were sold.

Scientific Review

The PMPRB's Human Drug Advisory Panel (HDAP) recommended that Enablex be reviewed as a category 3 new medicine (provides moderate, little or no therapeutic advantage).

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 World Health Organization (WHO) 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 flavoxate (Urispas), oxybutynin (Ditropan XL, Ditropan Syrup, PMS-Oxybutynin) and tolteridine (Detrol/Detrol LA) as the most appropriate comparators for Enablex (darifenacin). All these agents are administered orally, are indicated for the treatment of overactive bladder in adults and share the same 4th level ATC classification.

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 Enablex and the comparators are based on their respective product monographs, available comparative clinical trial information as well as guidelines relevant to the subject matter.

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 based on a TCC test, or if it exceeds the prices of the same medicine in the seven countries listed in the *Patented Medicines Regulations*. The prices of Enablex 7.5 mg/tablet and 15 mg/tablet were within the Guidelines as the daily cost of treatment did not exceed the daily cost of treatment of the comparator medicines. Furthermore, the Canadian prices of Enablex were the lowest of the four comparator countries in which they were sold.

Introductory Period (April to June 2006)

Name	Strength	Dosage Regimen	Unit Price	Cost Per Day
Enablex	7.5 mg/tablet	1 tablet	\$1.6671¹	1.6671
Urispas	200 mg	3 tablets	\$0.4940 ²	\$1.4820
PMS-Oxybutynin	5 mg	2 tablets	\$0.2485 ³	\$0.4970
Ditropan XL	5 mg	1 tablet	\$1.7500 ²	
+				
Ditropan XL	10 mg	1 tablet	\$1.7500 ²	\$3.5000
Ditropan Syrup	1 mg/mL	10 mL	\$0.0888 ³	\$0.8880
Detrol	2 mg	2 tablets	\$0.8750 ³	\$1.7500
Detrol LA	4 mg	1 tablet	\$1.7500 ³	\$1.7500

1. MEDIS McKesseeon Canada, May – July 2007
2. Liste de médicaments, Régie de l'assurance maladie du Québec, 15th Ed., Update 13, February 2006
3. Ontario Drug Benefit Formulary, No. 39, September 2005

Introductory Period (April to June 2006)

Name	Strength	Dosage Regimen	Unit Price	Cost Per Day
Enablex	15 mg/tablet	1 tablet	1.6671¹	\$1.6671
Urispas	200 mg	6 tablets	\$0.4940 ²	\$2.9640
PMS-Oxybutynin	5 mg	4 tablets	\$0.2485 ³	\$0.9940
Ditropan XL	10 mg	3 tablets	\$1.7500 ²	\$5.2500
Ditropan Syrup	1 mg/mL	20 mL	\$0.0888 ³	\$1.7760
Detrol	2 mg	2 tablets	\$0.8750 ³	\$1.7500
Detrol LA	4 mg	1 tablet	\$1.7500 ³	\$1.7500

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Where comparators and dosage regimens are referred to in the Summary Reports, they have been selected by 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 - Enablex

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19. Product Monograph of Detrol LA. E-CPS 2005.
20. Product Monograph of Ditropan . E-CPS 2005.
21. Product Monograph of Ditropan XL. E-CPS 2005.
22. Product Monograph of Oxytrol. E-CPS 2005.