

## Report on New Patented Drugs - Vesicare

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

**Brand Name:** Vesicare

**Generic Name:** (solifenacin succinate)

**DIN:** 02277263 5 mg/tablet  
02277271 10 mg/tablet

**Patentee:** Astellas Pharma Canada Inc.

### Indication - as per product monograph:

For the treatment of overactive bladder in adults with symptoms of urge urinary incontinence, urinary urgency, and urinary frequency.

**Date of Issuance of First Patent(s) Pertaining to the Medicine:** January 31, 2006

**Notice of Compliance:** February 20, 2006

**Date of First Sale:** June 24, 2006

**ATC Class:** GO4BD08  
*Genito Urinary System and Sex Hormones;  
Urologicals; Other Urologicals, incl. Antispasmodics;  
Urinary Antispasmodics*

## APPLICATION OF THE GUIDELINES

### Summary

The introductory prices of Vesicare 5 mg/tablet and Vesicare 10 mg/tablet were found to be within the Guidelines because their prices in Canada did not exceed the prices of existing drugs in the therapeutic class comparison and their prices did not exceed the prices of the same medicines in the other comparator countries where they were sold.

## Scientific Review

Vesicare is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) recommended that Vesicare be classified 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 4<sup>th</sup> level of the World Health Organization (WHO) Anatomical Therapeutic Chemical (ATC) classification 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 darifenacin (*Enablex*), flavoxate (*Urispas*), oxybutynin (*Ditropan XL, Ditropan Syrup, PMS-Oxybutynin*) and tolterodine (*Detrol, Detrol LA*) as the most appropriate comparators for Vesicare, as these therapeutic agents share the same 4<sup>th</sup> level ATC classification and indication as Vesicare, are administered orally, and are clinically equivalent in addressing the approved indication of Vesicare.

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 Vesicare and its 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 in the TCC test, or if it exceeds the prices of the same medicine in the seven countries listed in the *Patented Medicines Regulations, 1994* (Regulations). The prices of Vesicare 5 mg/tablet and Vesicare 10 mg/tablet were within the Guidelines as they were not considered to be excessive in relation to the prices of the comparator medicines.

### Introductory Period (July to December 2006)

Name	Strength	Dosage Regimen	Unit Price	Cost Per Day
<b>Vesicare</b>	<b>5 mg/tablet</b>	<b>1 tablet</b>	<b>\$1.6400<sup>1</sup></b>	<b>\$1.6400</b>
Enblex	7.5 mg tablet	1 tablet	\$1.6671 <sup>2</sup>	\$1.6671
Urispass	200 mg tablet	3 tablets	\$0.4940 <sup>3</sup>	\$1.4820
PMS-Oxybutynin	5 mg tablet	2 tablets	\$0.1973 <sup>4</sup>	\$0.3946
Ditropan Syrup	1 mg/mL	10 mL	\$0.0970 <sup>4</sup>	\$0.9700
Ditropan XL +	5 mg tablet	1 tablet	\$1.7500 <sup>3</sup>	\$3.5000
Ditropan XL	10 mg tablet	1 tablet	\$1.7500 <sup>3</sup>	
Detrol	2 mg tablet	2 tablets	\$0.9100 <sup>4</sup>	\$1.8200
Detrol LA	4 mg tablet	1 tablet	\$1.8200 <sup>4</sup>	\$1.8200

**Sources:**

1. Liste de Médicaments, Régie de l'assurance maladie du Québec, 17<sup>th</sup> Ed., June 2007
2. MEDIS Mckesson Canada, May – July 2007
3. Liste de Médicaments, Régie de l'assurance maladie du Québec, 15<sup>th</sup> Ed., Update 13, February 2006
4. Ontario Drug Benefit Formulary/ Comparative Drug Index: Electronic Version 1.3, June 2006

### Introductory Period (July to December 2006)

Name	Strength	Dosage Regimen	Unit Price	Cost Per Day
<b>Vesicare</b>	<b>10 mg/tablet</b>	<b>1 tablet</b>	<b>\$1.6400<sup>1</sup></b>	<b>\$1.6400</b>
Enblex	15 mg tablet	1 tablet	\$1.6671 <sup>2</sup>	\$1.6671
Urispass	200 mg tablet	6 tablets	\$0.4940 <sup>3</sup>	\$2.9640
PMS-Oxybutynin	5 mg tablet	4 tablets	\$0.1973 <sup>4</sup>	\$0.7892
Ditropan Syrup	1 mg/mL	20 mL	\$0.0770 <sup>4</sup>	\$1.5400
Ditropan XL	10 mg tablets	3 tablets	\$1.7500 <sup>3</sup>	\$5.2500
Detrol	2 mg tablet	2 tablets	\$0.9100 <sup>4</sup>	\$1.8200
Detrol LA	4 mg tablet	1 tablet	\$1.8200 <sup>4</sup>	\$1.8200

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In 2006, Vesicare 5 mg/tablet and Vesicare 10 mg/tablet were being sold in all of the seven countries listed in the Regulations. In compliance with the Guidelines, the prices of Vesicare 5 mg/tablet and Vesicare 10 mg/tablet in Canada were below the prices in other countries and were the lowest.

*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 - Vesicare**

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4. Cardozo L, Lisec M, Millard R, *et al.* Randomized, double-blind placebo controlled trial of the once daily antimuscarinic agent solifenacin succinate in patients with overactive bladder. *J Urol* 2004;172:1919-24.
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12. Kelleher C, Cardozo L, Kobashi K, *et al.* Solifenacin: as effective in mixed urinary incontinence as in urge urinary incontinence. *Int Urogynecol J Pelvic Floor Dysfunct* 2005.
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