

Report on New Patented Drugs - Abreva

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: Abreva
Generic Name: (*docosanol*)
DIN: 02245677 (10%, 100 mg/gram)
Patentee: GlaxoSmithKline Consumer Healthcare Inc.

Indication – as per product monograph:

For the treatment of acute episodes of recurrent oral-facial herpes simplex (fever blisters or cold sores) in adults.

Date of Issuance of First Patent(s)

Pertaining to the Medicine: June 29, 1999

Notice of Compliance: May 24, 2002

Date of First Sale: August 9, 2005

ATC Class: D06BB
Dermatologicals; Antibiotics and
Chemotherapeutics for Dermatological Use;
Chemotherapeutics for Topical Use; antivirals

APPLICATION OF THE GUIDELINES

Summary

The introductory price of Abreva was found to be within the Guidelines because the cost of therapy did not exceed the median of the international prices of the same medicine in the comparator countries listed in the *Patented Medicines Regulations* (Regulations) in which Abreva was sold.

Scientific Review

Abreva is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) recommended that Abreva be classified as a category 3 new medicine (provides moderate, little or no therapeutic advantage over comparable existing medicines).

The HDAP was unable to conclusively state that any one of the currently used medications for herpes labialis is clinically comparable. As a result, the HDAP did not identify any comparators for the conduct of a Therapeutic Class Comparison (TCC) test.

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 comparable drug products based on a TCC test, or if it exceeds the range of the prices of the same medicine sold in the seven countries listed in the Regulations.

The Guidelines further state that, when it is inappropriate or impossible to conduct a TCC test, Board Staff will give primary weight to the median of the international prices identified in an International Price Comparison (IPC) test. See the PMPRB's *Compendium of Guidelines, Policies and Procedures* for a more complete description of the Guidelines.

The introductory price of Abreva was within the Guidelines as the price in Canada did not exceed the median of the international prices identified in an IPC test as shown in the table below.

Introductory Period (August to December 2005)

Country and Median	Price (in Canadian dollars)
Canada	\$6.1150
France	--
Germany	--
Italy	--
Sweden	\$4.9476
Switzerland	--
United Kingdom	--
United States	\$7.6300
Median	\$6.2888

Source: Publicly available price as per the Regulations.

The publication of Summary Reports is part of the PMPRB's commitment to make its price review process more transparent.

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 PMPRB reserves the right to exclude from the therapeutic class comparison list any drug product if it has reason to believe it is being sold at an excessive price.

In its Summary Reports, the PMPRB will also refer to the publicly available prices of comparators provided such prices are not more than 10% above a non-excessive price in which case no price will be made available. As a result, the publication of these prices is for information purposes only and should not be relied upon as being considered within the Guidelines.

The information contained in the PMPRB's Summary Reports should not be relied upon for any purpose other than stated 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 – Abreva

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