

Report on New Patented Drug – Spriafil

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: Spriafil
Generic Name: (*posaconazole*)
DIN: 02293404 (40mg/ml dose)
Patentee: Schering-Plough Canada Inc.

Indication – as per product monograph:

SPRIAFIL (posaconazole) is indicated for:

- prophylaxis of Aspergillus and Candida infections in patients, 13 years of age and older, who are at high risk of developing these infections, such as patients with prolonged neutropenia or hematopoietic stem cell transplant (HSCT) recipients.
- treatment of invasive aspergillosis in patients 13 years of age or older with disease that is refractory to amphotericin B or itraconazole, or in patients who are intolerant of these medicinal products. Refractoriness is defined as progression of infection or failure to improve after a minimum of 7 days of prior therapeutic doses of effective antifungal therapy.
- treatment of oropharyngeal candidiasis (OPC) in patients 13 years of age or older.

Date of Issuance of First Patent(s)

Pertaining to the Medicine: January 23, 2007

Notice of Compliance: March 26, 2007

Date of First Sale: June 6, 2007

ATC Class: J02AC04
Antiinfectives for Systemic Use;
Antimycotics for systemic use;
Antimycotics for systemic use; Triazole
Derivatives

Application of the Guidelines

Summary

The introductory price of Spriafil was found to be within the Guidelines because the price in Canada did not exceed the median of the prices of the same drug in those countries listed in the *Patented Medicines Regulations, 1994* (Regulations) in which Spriafil was sold.

Scientific Review

Spriafil is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) recommended that Spriafil be classified as a category 2 new medicine. It provides a substantial improvement in the prevention of invasive fungal infections in immunocompromised patients, where current standard of prophylactic care confers inadequate protection.

The HDAP did not recommend any comparators for Spriafil; it is the first new active substance that offers significantly improved prophylactic coverage against invasive fungal infections.

Price Review

Under the Guidelines, the introductory price of a new category 2 drug product will be presumed to be excessive if it exceeds the prices of all comparable drug products, based on a Therapeutic Class Comparison (TCC) test, and 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.

It was not possible to conduct a TCC test as the HDAP did not identify any comparator drug products. At introduction, the price of Spriafil was within the Guidelines as it did not exceed the median of the international prices identified in an IPC test.

Introductory Period (June - July 2007)

Country Price per Dose (CDN)	
Canada	\$9.4095
France	n/a
Germany	\$9.9034
Italy	\$9.3453
Sweden	\$9.5354
Switzerland	\$9.4996
United Kingdom	\$10.0192
United States	\$4.8401
International Median	\$9.5175

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 - Spriafil

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