Report on New Patented Drugs – Trelstar LA

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: Trelstar LA

Generic Name: (*triptorelin pamoate*)

DIN: 02243856 (11.25 mg / vial)

Patentee: Paladin Labs Inc.

Indication - as per product monograph:

For the palliative treatment of hormone dependent advanced carcinoma of the prostate gland (Stage D2).

Date of Issuance of First Patent(s) Pertaining to the Medicine: January 25, 1994

Notice of Compliance: July 06, 2005

Date of First Sale: August 15, 2006

ATC Class: L02AE04
Antineoplastic and Immunomodulating Agents; Endocrine Therapy; Hormones and Related Agents; Gonadotropin releasing hormone analogues.

APPLICATION OF THE GUIDELINES

Summary

The introductory price of Trelstar LA 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 of the same medicine in the comparator countries listed in the *Patented Medicines Regulations, 1994* (Regulations) where Trelstar LA was sold.

Scientific Review

Trelstar LA is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) recommended that Trelstar LA be classified as a category 3 new medicine (provides moderate, little or no therapeutic 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 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 recommended Eligard PSF (*leuprolide acetate*), Lupron Depot PFS (*leuprolide acetate*), Suprefact (*buserelin acetate*), Zoladex (*goserelin acetate*), and Zoladex LA (*goserelin acetate*) as the most appropriate comparators to Trelstar LA (triptorelin pamoate). All these medications share the same 4th level ATC class, are indicated for the treatment of advanced cancer of the prostate and are considered clinically equivalent for this indication.

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 Trelstar LA and the comparable drug products were based on the respective product monographs and supported by clinical literature.

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

The Guidelines also provide that the PMPRB reserves the right to exclude from the TCC test any drug product it has reason to believe is being sold at an excessive price. At the time of this review the price of Eligard 45 mg was under investigation. It was therefore excluded from the TCC test.

The introductory price of Trelstar LA was within the Guidelines as the cost per treatment did not exceed the cost per treatment of the comparator medicines.

Introductory Period (August to December 2006)

Name	Strength	Dosage Regimen	Unit Price	Cost per Treatment (12 months)
Trelstar LA	11.25 mg	4 vials	$891.0000[(1)]	$3,564.0000
Eligard PFS	7.5 mg	12 vials	$343.5800[(2)]	$4,122.9600
Eligard PFS	22.5 mg	4 vials	$891.0000[(2)]	$3,564.0000
Eligard PFS	30 mg	3 vials	$1,285.2000[(2)]	$3,855.6000
Lupron Depot PFS	7.5 mg	12 vials	$387.9700[(2)]	$4,655.6400
Lupron Depot PFS	22.5 mg	4 vials	$1,071.0000[(2)]	$4,284.0000
Lupron Depot PFS	30 mg	3 vials	$1,428.0000[(2)]	$4,284.0000
Suprefact Depot	6.3 mg	6 vials	$670.0000[(2)]	$4,020.0000
Suprefact Depot	9.45 mg	4 vials	$990.0000[(2)]	$3,960.0000
Zoladex	3.6 mg	13 vials	$381.7500[(2)]	$4,962.7500
Zoladex LA	10.8 mg	4 vials	$1,087.9800[(2)]	$4,351.9200

Sources:
(1) Publicly available price as per the Regulations
(2) For all comparators, Ontario Drug Benefit Formulary, June 2006.

In 2006, Trelstar LA was being sold in one of the seven countries listed in the Regulations, namely the United States. In compliance with the Guidelines, the Canadian price was not the highest price.

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 – Trelstar LA

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