Report on New Patented Drugs – Bondronat

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 Price Guidelines, for all new active substances introduced after January 1, 2002.

Brand Name:	Bondronat
Generic Name:	ibandronate sodium
DIN:	02232770 1mg/ml 2ml ampoule for injection
Patentee:	Hoffmann-La Roche Limited
Indication - as per product monograph:	For the treatment of tumour-induced hypercalcemia with or without metastases.
Notice of Compliance:	June 8, 1998
Date of First Sale:	May 31, 2004
ATC Class:	M05BA06 *Drugs used for the treatment of bone diseases. Drugs affecting bone structure and mineralization; bisphosphonates*

Application of the Guidelines

Summary

Summary reports are available on our Web site under Patented Medicines; Reports on New Patented Drugs for Human Use.

The introductory price of Bondronat was found to be within the PMPRB's Guidelines because the cost of therapy did not exceed the cost of therapy of existing drugs in the therapeutic class comparison and the price did not exceed the range of prices in other comparator countries where Bondronat is sold.

Scientific Review

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

The HDAP identified Pamidronate (pamidronate disodium), Zometa (zoledronic acid) and Ostac or Bonefos (clodronate) as the most appropriate comparators for Bondronat. All these drug products share the same 4th level WHO ATC class and are indicated for the treatment of tumour-induced hypercalcemia.

The PMPRB's 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 Bondronat and the comparators are based on their 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 in the Therapeutic Class Comparison test, or if it exceeds the prices of the same medicine in the seven countries listed in the *Patented Medicines Regulations*.

The price of Bondronat was within the Guidelines as the cost of therapy did not exceed the cost of therapy with the comparator medicines.

In 2004, Bondronat was also sold in France, Germany, Sweden, Switzerland and the United Kingdom. In compliance with the Guidelines, the price in Canada did not exceed the range of prices in those countries. The price in Canada was the 3rd lowest, below the median international price.

Evidence/ References

The references are available on the PMPRB Web site, under Patented Medicines; Reports on New Patented Drugs for Human Use; Bondronat.

Name	Strength	Dosage Regimen	Cost of therapy
Bondronat	1mg/mL	4mL	$346.50[1]
Pamidronate	60mg/vial	2 vials	$569.90[2]
Zometa	4mg/vial	1 vial	$519.75[3]
Ostac	30mg/mL	100mL	$570.70[1]
Bonefos	60mg/mL	50mL	$590.00[1]

1. PPS, January 2005
2. Publicly available price as per the *Patented Medicines Regulations*
3. AQPP, October 2004

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. ■

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