

Reports on New Patented Drugs – Crestor

Brand Name:	Crestor
Generic Name:	rosuvastatin calcium
DIN:	02247162 10 mg tablet 02247163 20 mg tablet 02247164 40 mg tablet
Patentee:	AstraZeneca Canada Inc.
Indication – as per product monograph:	As an adjunct to diet, at least equivalent to the Adult Treatment Panel III (ATP III TLC diet), for the reduction of elevated total cholesterol, LDL-cholesterol, ApoB, the total cholesterol; HDL-cholesterol ratio and triglycerides and for increasing HDL-C; in hyperlipidemic and dyslipidemic conditions, when response to diet and exercise alone has been inadequate including: primary hypercholesterolemia, combined dyslipidemia, and homozygous familial hypercholesterolemia.
Notice of Compliance:	February 18, 2003
Date of First Sale:	February 19, 2003
ATC Class:	C10AA07 <i>Serum lipid reducing agents</i> <i>Cholesterol and triglyceride reducers</i> <i>HMG CoA reductase inhibitors</i>

Application of the Guidelines

Summary:

The introductory prices of Crestor were 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 the prices did not exceed the range of prices in other comparator countries where Crestor was sold.

Scientific Review:

Crestor is a new active substance and the PMPRB's Human Drug Advisory Panel (HDAP) recommended that Crestor be reviewed 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 4th level of the 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.

Other agents in the same 4th level ATC class, HMG-CoA reductase inhibitors (commonly known as 'statins'), available on the Canadian market, include Zocor (simvastatin), Mevacor (lovastatin), Pravachol (pravastatin), Lescol (fluvastatin), and Lipitor (atorvastatin). These statins share similar indications, have been compared directly to Crestor in clinical trials, and are referred to interchangeably in the U.S. and Canadian dyslipidemia guidelines.

In its review of Crestor, the HDAP noted that the lipid lowering effects of statins have increased, with Crestor having the greatest impact on lipid levels. The recommended comparable dosage regimens for Crestor were based on the comparative clinical trial data identified (see Evidence/References).

For purposes of the Guidelines, the HDAP attempted to identify comparable dosages of the other statins, but this was not always possible because of the greater efficacy of Crestor in lowering lipid levels. The table below shows the range of costs of treatment with the statins included in the TCC based on the range of approved dosages.

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.

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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 TCC test, or if it exceeds the prices of the same medicine in the seven countries listed in the *Patented Medicines Regulations*. The price of Crestor was within the Guidelines as the daily cost of therapy did not exceed the cost of therapy with the comparator medicines.

Name	Dosage Regimen/day	Cost Per Day ¹
Crestor (rosuvastatin calcium)	10-40 mg	\$1.36 - \$1.99
Zocor (simvastatin) <i>generic simvastatin</i> ²	10-80 mg 10-80 mg	\$1.78 - \$2.20 \$1.25 - \$1.54
Mevacor (lovastatin) <i>generic lovastatin</i> ³	20-80 mg 20-80 mg	\$1.73 - \$6.39 \$1.09 - \$4.02
Lipitor (atorvastatin)	10-80 mg	\$1.60 - \$2.15

1 Liste de médicaments du Québec, October 2003
2 There are four manufacturers of this generic medication.
3 There are seven manufacturers of this generic medication.

Evidence/ References:

The references are available on the PMPRB website, under Publications, Patented Medicines; Reports on New Patented Drugs; Crestor.

In 2003, Crestor 10 mg, 20 mg and 40 mg tablets were also being sold in the United Kingdom and the United States. In compliance with the Guidelines, the price in Canada did not exceed the range of prices in those countries; the prices of Crestor 20 mg and 40 mg were lower than the prices in those countries and the price of Crestor 10 mg was second lowest, below the median of international prices.