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### **CRESTOR SAFETY INFORMATION**

**WINNIPEG, March 8<sup>th</sup>, 2005** – Health Canada has released new safety information and requested changes to the product monograph related to AstraZeneca Canada's lipid-lowering agent, Crestor®. An initial safety advisory warning health care professionals of an association between the use of Crestor® and rhabdomyolysis (an acute, potentially fatal disease of skeletal muscle) was made public in June 2004. A second advisory was made public in November 2004 identifying an increase in the reported rate of rhabdomyolysis associated with use of the Crestor® 40mg daily dose.

The changes to the product monograph include:

- Contraindication of the 40mg once daily dose in patients with predisposing risk factors for myopathy (any disease of muscular tissue) or rhabdomyolysis
- Recommendation that the 40mg once daily dose be initiated under specialist supervision
- Recommendation of a new lower 5mg once daily starting dose for Asian patients and patients with severe renal impairment
- Initiation of therapy with Crestor® 5mg once daily to be considered for patients requiring less aggressive LDL cholesterol reductions

Predisposing factors for myopathy/rhabdomyolysis include:

- Personal/family history of hereditary muscle disorders
- Concomitant use of a fibrate drug or niacin
- Severe liver impairment
- Severe kidney impairment
- Hypothyroidism
- Alcohol abuse
- Asian patients (based on information from a recent US study conducted)



## **Crestor Therapy Dosing**

The recommended starting dose for Crestor® in most patients is 10mg once daily. Most patients achieve recommended target lipid levels at this dose. A new recommendation for initiation of therapy with Crestor® 5mg once daily is made for Asian patients, and patients with severe liver impairment.

A 5mg Crestor® tablet is being introduced onto the Canadian market in May 2005. As a result, initiation of therapy with Crestor® 5mg once daily may be considered for patients requiring less aggressive LDL cholesterol reductions or who have predisposing factors for myopathy.

