Health Canada Santé Canada

Date issued December 4, 2006

NOTICE OF DECISION for ROTATEQ™

On August 1, 2006, Health Canada issued a Notice of Compliance to Merck Frosst Canada Ltd. for the vaccine RotaTeq™.

RotaTeq™ is a live, oral, pentavalent vaccine for use in the prevention of rotavirus gastroenteritis. RotaTeq™ contains as active ingredients, five live reassortant rotaviruses.

RotaTeq™ is indicated for the prevention of rotavirus gastroenteritis caused by the serotypes G1, G2, G3, G4, and G-serotypes that contain P1[8], when administered to infants. Rotavirus is the leading cause of severe acute gastroenteritis in infants and young children in industrialized and developing countries. If left untreated, rotavirus gastroenteritis may cause dehydration that can be fatal. Protection from natural rotavirus infection is largely serotype specific. The human rotavirus serotypes included in RotaTeq™ were selected based on historical evidence that these strains caused nearly 90% of rotavirus disease in North America, Europe, and Australia and over 88% of rotavirus disease worldwide between 1973 and 2003. The exact immunological mechanism by which RotaTeq™ protects against subsequent rotavirus illnesses is not well defined. Studies suggest a combination of factors contribute to the development of rotavirus immunity generated by the vaccine.

The market authorization for RotaTeq™ was based on quality, pre-clinical, and clinical information submitted. Overall, 71 942 healthy infants were randomized worldwide in three pivotal, placebo-controlled, Phase III studies. Data demonstrating the efficacy of RotaTeq™ in preventing rotavirus gastroenteritis came from 6 983 of these infants from the United States and Finland who were enrolled in two of these studies. RotaTeq™ was efficacious against naturally-occurring rotavirus gastroenteritis of any severity caused by the composite of the serotypes contained within the vaccine occurring at least 14 days following the third vaccination. The efficacy of RotaTeq™ persisted through the first and second rotavirus seasons following vaccination.

RotaTeq™ (rotavirus vaccine, live, oral, pentavalent) is presented as a single, pre-filled, 2 mL unit dose in a plastic dosing tube with a twist-off cap. The vaccination series consists of three ready-to-use liquid doses of RotaTeq™ administered orally to infants. The first dose of RotaTeq™ should be administered at 6 to 12 weeks of age. Further dosing guidelines are available in the Product Monograph.

RotaTeq™ is contraindicated for patients who are hypersensitive to this vaccine or to any ingredient in the formulation or any component of the container. For a complete listing, see the Dosage Forms, Composition and Packaging section of the Product Monograph. Individuals who develop symptoms suggestive of hypersensitivity after receiving a dose of RotaTeq™ should not receive further doses of RotaTeq™. RotaTeq™ should be administered under the conditions stated in the Product Monograph taking into consideration the potential risks associated with the administration of this vaccine. Detailed conditions for the use of RotaTeq™ are described in the Product Monograph.

Based on the Health Canada review of data on quality, safety, and effectiveness, Health Canada considers that the benefit/risk profile of RotaTeq™ is favourable for the prevention of rotavirus gastroenteritis caused by the serotypes G1, G2, G3, G4, and G-serotypes that contain P1[8], when administered to infants.

Notices of Decision (NDs) are produced in accordance with the Summary Basis of Decision (SBD) initiative. All NDs will be reproduced within the corresponding SBD, normally available within 5 months of product authorization.