



## **RotaTeq™**

### **Fact Sheet**

#### **Approved indication**

RotaTeq™ (rotavirus vaccine, live, oral, pentavalent) is a vaccine indicated for the prevention of rotavirus gastroenteritis in infants and children caused by the serotypes G1, G2, G3, G4 and G-serotypes that contain P1[8].<sup>1</sup>

Similar indications for RotaTeq™ were approved earlier in the US, Mexico, European Union and Australia.

#### **How RotaTeq™ works**

RotaTeq™ is a new vaccine that effectively prevents rotavirus, a viral infection that may cause vomiting, diarrhea, fever and dehydration.<sup>1</sup> Protection from natural rotavirus infection is largely strain specific and RotaTeq™ works by helping the body develop natural defenses against the most common strains of the virus. RotaTeq™ includes the human rotavirus serotypes (G1, G2, G3, G4, and P1[8]) because these strains caused nearly 95 per cent of rotavirus disease in Canada<sup>2</sup> and over 88 per cent of rotavirus disease worldwide between 1973 and 2003.<sup>1,3</sup>

#### **Proven effectiveness**

Worldwide, 71,942 healthy infants were studied in three, randomized, placebo-controlled studies examining both the efficacy and safety of RotaTeq™. The effect of RotaTeq™ on hospitalizations and emergency department visits for rotavirus gastroenteritis was also evaluated in the Rotavirus Efficacy and Safety Trial (REST). In these studies, RotaTeq™ prevented 98 per cent of severe cases of rotavirus and 74 per cent of all cases, regardless of the severity. RotaTeq™ also reduced the need for hospitalization due to rotavirus gastroenteritis by 96 per cent.<sup>1</sup>

#### **Proven tolerability**

Administration of RotaTeq™ was well tolerated, even when given with other childhood vaccines such as diphtheria and tetanus. Rates of serious adverse events were similar in infants receiving RotaTeq™ compared to infants who were not administered the vaccine. The side effects reported with the use of RotaTeq™ were diarrhea, vomiting, fever, runny nose and sore throat, wheezing or coughing, and ear infection and were similar compared to infants given a placebo.<sup>1</sup>

## **Administration**

The RotaTeq™ vaccine consists of three ready-to-use liquid doses administered orally to infants between six and 32 weeks of age. The first dose should be given between six to 12 weeks of age and the two additional doses should be administered at four to 10 week intervals. RotaTeq™ may be given to pre-term infants according to their chronological age.<sup>1</sup>

## **Availability of RotaTeq™**

RotaTeq™ should be available this fall through Canadian physicians and pharmacists at a list price of \$55 per dose.

## **References**

1. Health Canada approved product monograph for RotaTeq™
2. Kostouros E et al. Molecular characterization of rotavirus strains from children in Toronto, Canada. *J Clin Virol* 2003;28(1):77-84
3. Griffin DD, Kirkwood CD, Parashar UD, Woods PA, Bresee JS, Glass RI, et al. Surveillance of rotavirus strains in the United States: identification of unusual strains. *J Clin Microbiol* 2000;38(7):2784-7