

Rotarix? (RIX4414): An oral human rotavirus vaccine

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Rotavirus is the most common cause of severe gastroenteritis in children younger than 3 years of age worldwide. New rotavirus vaccine candidates were required to confer early protection against the most common rotavirus serotypes and to be well tolerated and not associated with intussusception. RIX4414 is a human-attenuated G1(P8) oral rotavirus vaccine administered in two doses at approximately 6-24 weeks of age. The first dose may be administered from the age of 6 weeks. There should be an interval of at least 4 weeks between doses and the vaccination course should preferably be given before 16 weeks of age and must be completed, according to the manufacturer, by the age of 24 weeks. In a worldwide development program involving more than 70,000 children in six Phase I-III field trials, this vaccine proved to be nonreactogenic, well tolerated and not associated with intussusception. The vaccine provides over 85-96% protection against moderate-to-severe gastroenteritis caused by G1 and