

Information on Rotarix Vaccine

The Bureau of Immunization wishes to bring to your attention the following information concerning prescribing information and patient labeling for Rotarix vaccine, manufactured by GlaxoSmithKline.

FDA has added information to the existing intussusception subsection of the Warnings and Precautions section of the Rotarix vaccine label to inform healthcare providers about preliminary results from a postmarketing study conducted in Mexico. An interim analysis of this study suggests an increased risk of intussusception in the 31 day time period after the first dose of Rotarix (relative risk of 1.8 with a 99% confidence interval of 1.0 to 3.1).

For the United States, these findings translate to potentially 0-4 additional cases of intussusception hospitalizations per 100,000 infants within 31 days of receiving the first dose of Rotarix. This takes into consideration the background rate of intussusception hospitalizations in the United States, which is approximately 34 in 100,000 infants per year.

Further analysis showed that the increased number of intussusception cases occurred primarily within seven days after the first dose.

This information has also been included in the Postmarketing Experience subsection of the Adverse Reactions section of the prescribing information and in the information for the patient.

No changes have been made to the Contraindications or Indications for Use of Rotarix.

The approval letter, package insert and Q&A on the Rotarix label revision can be found on FDA's website at:

<http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm133920.htm>. The Q&A can be found directly at this link:

<http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm226690.htm>.

Commonly asked Q&As are on CDC's website for healthcare professionals and parents at the following links: <http://www.cdc.gov/vaccines/vpd-vac/rotavirus/Vac-label-hcp.htm> and <http://www.cdc.gov/vaccines/vpd-vac/rotavirus/Vac-label-parents.htm>.

Please distribute this important information to colleagues, members, coalitions, and partners who provide or have an interest in immunizations. Please place this information prominently on your website. Contact Laura Rutledge, RN regarding vaccine recommendations or Bob Griffin regarding the VFC program at (850) 245-4342.

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