

Landmark Rh Immune Globulin Celebrates 40 Years of Saving Babies' Lives

RhoGAM® Brand Hailed as One of the Top Achievements in 50 Years of Women's Health

RARITAN, N.J., (February 9, 2009) – RhoGAM® Brand, the original Rh immune globulin product, celebrates its 40th year in the marketplace helping Rh-negative women in the prevention of Hemolytic Disease of the Newborn (HDN). In 1968, a new mother at Holy Name Hospital in Teaneck, N.J., helped make history as the initial recipient of the world's first injectable treatment to prevent the disease — an event that marked the launch of one of the most significant medical breakthroughs of the 20th century. Prior to the introduction of RhoGAM® Brand, nearly 10,000 babies died each year in the U.S. alone from HDN.¹

“Today, this condition has been substantially reduced due to the safe and effective use of Rh immune globulin products, saving hundreds of thousands of newborns from crippling birth defects and possible death,” said Ronald T. Burkman, MD, attending physician at Wesson Women's Group, Baystate Medical Center and Professor of Obstetrics and Gynecology, Tufts University School of Medicine.

About HDN

HDN can develop when the Rh-negative blood of a pregnant woman comes in contact with the Rh-positive blood of her fetus. These Rh-negative women become sensitized and make antibodies that attack the blood of the Rh-positive fetus.² This reaction usually does not affect the first pregnancy, but once the mother has produced Rh antibodies, all future pregnancies are at risk.

“It is still important for women, as part of their prenatal care, to have a blood test and find out their blood type,” continued Dr. Burkman.

About RhoGAM® Brand

Rh immune globulin products prevent the body from making antibodies that would destroy Rh-positive cells in future pregnancies and cause HDN to develop. RhoGAM® Brand has maintained a 40-year record of proven safety, efficacy and uninterrupted product supply, due in part to its unique donor program. Plasma for RhoGAM® Brand is sourced from a small collection site near Buffalo, N.Y. made up of approximately 300 participants. One third of the donors have been contributing to the program for more than 10 years, and some have personal reasons for doing so.

“My primary reason is simple — I want to spare other Rh-negative expecting mothers from what I went through before RhoGAM[®] Brand was introduced,” said Elizabeth Pascoe, a plasma donor for 30 years who has helped save potentially 115,000 babies’ lives. “Sometimes I worry that people forget how dreadful this disease can be. I am truly grateful that my children and future generations have a way to protect against Hemolytic Disease of the Newborn.”

The development of RhoGAM[®] Brand was the result of years of collaborative work by researchers at Columbia University in New York and the Ortho Research Foundation (now Ortho Clinical Diagnostics) in Raritan, N.J. When it was launched, RhoGAM[®] Brand was heralded as an obstetrical milestone. Charles Lockwood, MD, former chair of the American College of Obstetricians and Gynecologists’ (ACOG) Committee on Obstetric Practice, has hailed RhoGAM[®] Brand as “one of the top achievements in 50 years of women’s health.”

Important Safety Information

RhoGAM[®] and MICRhoGAM[®] Ultra-Filtered PLUS Rho(D) Immune Globulin (Human) are made from human plasma. Since all plasma-derived products are made from human blood, they may carry a risk of transmitting infectious agents, e.g., viruses, and theoretically the Creutzfeldt-Jakob disease (CJD) agent. RhoGAM[®] and MICRhoGAM[®] are intended for maternal administration. Do not inject the newborn infant. Local adverse reactions may include redness, swelling, and mild pain at the site of injection and a small number of patients have noted a slight elevation in temperature. Patients should be observed for at least 20 minutes after administration. Hypersensitivity reactions include hives, generalized urticaria, tightness of the chest, wheezing, hypotension and anaphylaxis. RhoGAM[®] and MICRhoGAM[®] contain a small quantity of IgA and physicians must weigh the benefit against the potential risks of hypersensitivity reactions. Patients who receive RhoGAM[®] and MICRhoGAM[®] for Rh-incompatible transfusion should be monitored by clinical and laboratory means due to the risk of a hemolytic reaction.

For more detailed information regarding the safe and effective use of RhoGAM[®] Brand, please visit www.RhoGAM.com.

About Ortho Clinical Diagnostics

Ortho-Clinical Diagnostics, Inc., a Johnson & Johnson company, delivers the high-quality in-vitro diagnostic products that give healthcare professionals around the world the knowledge they need to make better

treatment decisions sooner. The company serves the global transfusion medicine community with donor screening and blood typing products to ensure every patient receives blood that's safe, the right type, and the right unit. Ortho Clinical Diagnostics also brings sophisticated information management, testing technologies, and automation and interpretation tools to clinical laboratories worldwide to help them run more efficiently and improve patient care. For more information, visit www.orthoclinical.com.

¹ Zimmerman D.R. *Rh: The Intimate History of a Disease and its Conquest*. New York, NY: MacMillan Publishing Company, May 1973.

² www.acog.org/publications/patient_education/bp027.cfm

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