

Your baby's life story

The original Rh-negative breakthrough that has protected generations of babies.^{1.4} What is RhoGAM?

RhoGAM Ultra-Filtered PLUS [Rho(D) Immune Globulin (Human)] is a prescription medicine given by intramuscular injection that is used to prevent Rh immunization, a condition in which a person with Rh-negative blood develops antibodies after exposure to Rh-positive blood.

_____ ORIGINAL

ANTI-D BRAND



When is RhoGAM used?

If you are Rh-negative, and the father or baby is not conclusively Rh-negative, it is routine for you to receive RhoGAM twice:

- At 26 to 28 weeks of pregnancy
- · After delivery of an Rh-positive baby

Other times of prevention

- Maternal or fetal bleeding during pregnancy from certain conditions
- Actual or threatened pregnancy loss at any stage
- Ectopic pregnancy (pregnancy in which the fertilized egg implants outside the uterus)
- Amniocentesis
- Chorionic villus sampling (CVS)
- Manipulative procedures (such as for a breech presentation)
- Other obstetrical trauma

Learning that you are Rh-negative

Pregnancy is a very exciting time. This is also the first time most women learn their blood type. You just learned that you are Rh-negative and you probably have a lot of questions like, "What does this mean for me and my baby?"

The goal of this brochure is to help you learn how RhoGAM could help protect you and your baby and to answer questions you may have.

Important Safety Information about RhoGAM

RhoGAM should NOT be used if you are Rh-positive or if you have had a severe allergic reaction to human immune globulin.

Be sure to tell your healthcare provider about all your medical conditions, including:

- If you have ever had a severe allergic reaction or a severe response to human immune globulin.
- If you have an immunoglobulin A (IgA) deficiency. RhoGAM contains a small quantity of IgA and there is a potential risk of an allergic reaction in IgA-deficient individuals. Ask your healthcare provider if you are not sure.
- Your recent history of vaccinations. Certain types of vaccines (ones containing a live virus) may not work as well for you if you are also receiving immune globulin products like RhoGAM. The antibodies in RhoGAM may prevent the vaccine from working. Before you get a vaccine, tell your healthcare provider that you have received RhoGAM.

See additional Important Safety Information at the end of this brochure.





Understanding your blood type: what it means to be Rh-negative

Rh Factor

The Rh factor is an antigen, or protein, found on the surface of red blood cells. Rh is the abbreviation for rhesus, which is the name of one of many different blood group systems in the body.



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Rh-positive people have the Rh antigen (also called D antigen) on the surface of their red blood cells

Rh-negative people do not have the Rh antigen on the surface of their red blood cells

Rh-incompatibility: what does this mean?



Approximately 15% of women are Rh-negative²

When an Rh-negative mother carries an Rh-positive baby, and some of the baby's blood enters the mother's bloodstream, this is called Rh-incompatibility. The mother's immune system sees the baby's red blood cells as "foreign" and will try to eliminate them by making anti-Rh antibodies. These antibodies can cross the placenta and attack the fetus's blood cells.

Rh-incompatibility usually does not affect the mother's first baby, because her body does not have time to produce enough antibodies. But once she has produced an immune response, or Rh sensitization, all future Rh-positive babies are at risk for developing hemolytic disease of the fetus and newborn (HDFN).



When can Rh sensitization occur?

Rh sensitization can occur when a small amount of blood from the fetus mixes with the mother's blood. This may happen during the following:

- Delivery
- Amniocentesis
- Chorionic villus sampling (CVS)
- · Manipulative procedures (such as for a breech presentation)
- Miscarriage
- Ectopic pregnancy (pregnancy in which the fertilized egg implants outside the uterus)
- Other obstetrical trauma

Rh sensitization can lead to hemolytic disease of the fetus and newborn (HDFN)

HDFN is caused when the mother's immune system tries to destroy her baby's red blood cells. HDFN does not affect the mother, but it is a serious condition that affects the fetus and/or newborn and may cause:

- · Anemia (low red blood cell count)
- Jaundice (yellowing of the skin and whites of eyes due to red blood cell breakdown)
- Heart failure
- Possible brain damage

Without prevention, HDFN can have serious effects on the baby

Preventing HDFN is better than needing to treat it because of the serious problems that can occur. When RhoGAM was first introduced in 1968, a single dose after delivery was found to lower the rate of Rh sensitization by 90%.² But a small number of women were still becoming Rh sensitized for unknown reasons. Further studies found that Rh sensitization occurs at times other than just at delivery, but this can be reduced by 99% if Rh-negative mothers receive an anti-D therapy before delivery at 28 weeks.^{23,6}



HOW HDFN DEVELOPS

Hemolytic Disease of the Fetus and Newborn



Sometimes a baby's Rh-positive red blood cells enter the Rh-negative mother's bloodstream



The mother produces antibodies against the baby's red blood cells. Usually, these antibodies do not affect her first baby, but future Rh-positive babies are at risk



If the second baby is Rh-positive, the mother's antibodies will destroy the baby's red blood cells, putting the baby at risk for HDFN



RhoGAM is an intramuscular injection that helps to prevent the production of antibodies (Rh sensitization). Rh sensitization can lead to hemolytic disease of the fetus and newborn (HDFN) in future pregnancies. If given to you at the right time, RhoGAM will prevent your immune system from reacting to your baby's blood.



RhoGAM prevents the Rh-negative expectant mother from making antibodies during pregnancy that could cause HDFN in future pregnancies



As long as the Rh-negative mother receives RhoGAM appropriately during every pregnancy, her babies are at very low risk of developing HDFN

Approved Uses

RhoGAM® Ultra-Filtered PLUS [Rho(D) Immune Globulin (Human)] 300 µg) is a prescription medicine given by intramuscular injection that is used to prevent Rh immunization, a condition in which an individual with Rh-negative blood develops antibodies after exposure to Rh-positive blood.

If the father or baby is not conclusively shown to be Rh-negative, RhoGAM should be given to an Rh-negative mother in the following clinical situations to prevent Rh immunization:

- · After delivery of an Rh-positive baby
- Routine prevention of Rh immunization at 26 to 28 weeks
- Maternal or fetal bleeding during pregnancy from certain conditions
- · Actual or threatened pregnancy loss at any stage
- Ectopic pregnancy (pregnancy in which the fertilized egg implants outside the uterus)

Important Safety Information (continued)

Allergic reactions to RhoGAM may occur. You should be observed for at least 20 minutes after administration. Signs and symptoms of an allergic reaction include itchy rash (hives/urticaria), tightness of the chest, wheezing, low blood pressure and anaphylaxis (which may also include throat or tongue swelling, shortness of breath, vomiting, hives and/or lightheadedness).

RhoGAM is prepared from human plasma and may contain infectious agents that can cause disease. Numerous tests have been applied in the plasma collection process and specific viral inactivation steps have been added to the manufacturing process to minimize the risk of transmission of diseases, but all risk cannot be eliminated.

Please see accompanying Full Prescribing Information for RhoGAM.

Receiving RhoGAM



Why RhoGAM?

It provides protection as early as 26-28 weeks of your pregnancy.⁷

Studies have found that the most effective way to reduce Rh sensitivity is to receive anti-D therapy at 28 weeks of pregnancy.^{24,8}



RhoGAM has the longest half-life of other anti-D products.⁹

Half-life is the indicator of how long RhoGAM circulates in your system; the longer the half-life, the longer the protection.¹⁰ RhoGAM's half-life means that if you receive it after 26 weeks, it will continue to protect the baby until delivery.



RhoGAM's half-life aligns with the American College of Obstetricians and Gynecologists (ACOG)¹¹

RhoGAM helped set the standards and clinical practice guidelines that are still followed today.



RhoGAM has remained a reliable choice for 5 decades as the first anti-D product available.¹

Talk to your healthcare provider to learn about how RhoGAM may help protect you and your baby during your pregnancy.

Please see accompanying Full Prescribing Information for RhoGAM.



In most cases, you will receive a dose of RhoGAM between 26-28 weeks of pregnancy.

During pregnancy, the baby's Rh blood type can only be determined through invasive procedures. Since the Rh-positive blood type is much more common than Rh-negative, most physicians will administer RhoGAM without determining the blood type of the baby during pregnancy.



If your baby is found to be Rh-positive at birth, you will receive a second dose of RhoGAM within 72 hours after delivery.*

If your baby is determined to be Rh-negative at birth, you do not need an additional dose of RhoGAM. *Your doctor will determine the appropriate dose of RhoGAM after delivery.

At any time during your pregnancy, be sure to notify your healthcare provider immediately if you have vaginal bleeding or experience any abdominal trauma. You may need an additional dose of RhoGAM.

RhoGAM is available by prescription only and can only be administered by a healthcare provider.

RhoGAM is intended for maternal administration only and should not be injected into the newborn infant.

The most common side effects of RhoGAM are swelling, hardening, redness, and mild pain at the site of the injection. A small number of patients have noted a slight fever.

Your healthcare provider should provide you with a completed Patient Identification Card for you to retain and present to other healthcare providers.



Welcome to the RhoGAM family

Your RhoGAM Patient Identification Card

You should receive a Patient Identification Card* after each RhoGAM injection. Please be sure to ask your healthcare provider if you do not receive one. *For sample purposes only, actual card may differ



For more information about RhoGAM, visit RhoGAM.com

Important Safety Information

RhoGAM or MICRhoGAM should NOT be used if you are Rh-positive or if you have had a severe allergic reaction to human immune globulin.

Be sure to tell your healthcare provider about all your medical conditions, including:

- If you have ever had a severe allergic reaction or a severe response to human immune globulin.
- If you have an immunoglobulin A (IgA) deficiency. RhoGAM contains a small quantity of IgA and there is a potential risk of an allergic reaction in IgA-deficient individuals. Ask your healthcare provider if you are not sure.
- Your recent history of vaccinations. Certain types of vaccines (ones containing a live virus) may not work as well for you if you are also receiving immune globulin products like RhoGAM. The antibodies in RhoGAM may prevent the vaccine from working. Before you get a vaccine, tell your healthcare provider that you have received RhoGAM.

Allergic reactions to RhoGAM may occur. You should be observed for at least 20 minutes after administration. Signs and symptoms of an allergic reaction include itchy rash (hives/urticaria), tightness of the chest, wheezing, low blood pressure and anaphylaxis (which may also include throat or tongue swelling, shortness of breath, vomiting, hives and/or lightheadedness).

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You are encouraged to report adverse event of prescription drugs to the FDA. Visit www.fda.gov/Safety/MedWatch/ or call 1-800-FDA-1088.

Please see accompanying Full Prescribing Information for RhoGAM or visit RhoGAM.com for more information.

References: 1. Data on File. Kedrion Biopharma Inc. 2. Bowman JM. The prevention of Rh immunization. *Transfus Med Rev.* 1988;2:129-150. 3. Hartwell EA. Use of Rh immune globulin. ASCP practice parameter. *Am J Clin Pathol.* 1998;110:281-92. 4. Bowman JM, Pollock JM. Antenatal prophylaxis of Rh isoimmunization: 28-weeks' gestation service program. *Can Med Assoc J.* 1978;118:627-30. 5. The plasma proteins market in the United States, 2017. The Marketing Research Bureau. Orange, CT: 2018. 6. Bowman JM, Chown B, Lewis M, Pollock JM. Rh isoimmunization during pregnancy: antenatal prophylaxis. *Can Med Assoc J.* 1978;118:623-7. 7. RhoGAM Ultra-Filtered PLUS [prescribing information]. Fort Lee, NJ. Kedrion Biopharma Inc. 2019.
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Your baby's life story begins with RhoGAM



Since RhoGAM's introduction in 1968, the incidence of Rh-sensitization has decreased dramatically²⁻⁴

RhoGAM takes pride in an excellent safety and quality record

- Unique plasma donor program dedicated to RhoGAM
- Manufacturing process designed to remove viruses
- No documented cases of viral transmission in over 50 years¹

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You should consult with your healthcare provider if you have any questions or concerns.

See additional Important Safety Information about RhoGAM inside this brochure.

URIGINAL ORIGINAL #1 SELLING ANTI-D BRAND⁵

BE SURE TO ASK FOR RhoGAM BRAND For more information, please visit RhoGAM.com

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