You’re pregnant and you’re Rh-negative

Talk to your doctor to learn how RhoGAM® may help protect you and your baby.
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 may help protect you and your baby and to answer any questions you may have.

Understanding your blood type

Rh is the abbreviation for rhesus, which is the name of one of many different blood group systems in the body.

> **Rh-positive** people have the Rh antigen (also called rhesus factor or 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

Important Safety Information

RhoGAM® Ultra-Filtered PLUS [Rh0(D) Immune Globulin (Human)] (300 µg) is indicated for the prevention of Rh immunization, including during and after pregnancy and other obstetrical conditions or incompatible transfusion of Rh-positive blood.

RhoGAM® is 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.

What does it mean for you and your baby?

During pregnancy, it is normal for a small amount of the baby’s blood to enter the mother’s bloodstream.

When an Rh-negative mother carries an Rh-positive baby 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 as invaders.

Rh-incompatibility usually does not affect the mother’s first baby, but once she has produced an immune response (called “Rh-sensitization”), all future Rh-positive babies are at risk for developing hemolytic disease of the fetus and newborn (HDFN). For the newborn, HDFN is a serious condition that may cause anemia (low red blood cell count), jaundice, and in severe cases, heart failure and possible brain damage.

Next, learn more about RhoGAM and how it may help prevent HDFN
HDFN before RhoGAM

Before RhoGAM, thousands of babies each year were affected by HDFN. In 1968, RhoGAM was introduced as the first anti-D Rho(D) Immune Globulin (Human), and within a short time, helped to virtually eliminate HDFN.¹

Important Safety Information

RhoGAM® Ultra-Filtered PLUS [Rh(D) Immune Globulin (Human)] (300 µg) is indicated for the prevention of Rh immunization, including during and after pregnancy and other obstetrical conditions or incompatible transfusion of Rh-positive blood.

RhoGAM® is 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® is 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.

When you’ll receive RhoGAM

RhoGAM is an injection that will be given by your doctor.

➢ You will receive a dose of RhoGAM between 26-28 weeks of pregnancy

➢ If your baby is found to be Rh-positive at birth, you will receive a second dose 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

At any time during your pregnancy, be sure to notify your physician 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.

Please talk to your doctor to find out if RhoGAM is right for you.

After the introduction of RhoGAM, anti-D was hailed as one of the greatest discoveries in obstetrics and gynecology²
How does RhoGAM work?

> RhoGAM helps prevent the production of antibodies that lead to HDFN.

How HDFN develops:

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 a second baby is Rh-positive, the mother’s antibodies will try to destroy the baby’s red blood cells, putting the baby at risk for HDFN

How RhoGAM works:

RhoGAM prevents the Rh-negative mother from making antibodies during her first 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

Important Safety Information

RhoGAM® Ultra-Filtered PLUS [Rho(D) Immune Globulin (Human)] (300 µg) is 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.

RhoGAM® contains a small quantity of IgA and physicians must weigh the benefit against the potential risks of hypersensitivity reactions. Hypersensitivity reactions include hives, generalized urticaria, tightness of the chest, wheezing, hypotension and anaphylaxis. Patients who receive RhoGAM® for Rh-incompatible transfusion should be monitored by clinical and laboratory means due to the risk of hemolytic reaction.
RhoGAM Patient Identification Card

You should receive a patient identification card after each RhoGAM injection. Please be sure to ask your doctor if you do not receive one.

- **Date of Injection of RhoGAM**: 07/01/15
- **Lot No.**: 12345
- **Exp. Date**: 12/31/15
- **Injection was**: ☑ during pregnancy
- **Attending Physician**: Dr. Sample
- **Physician’s Telephone Number**: (555)555-5555

*For sample purposes only, actual card may differ*

For more information about RhoGAM visit www.RhoGAM.com

Since 1968, RhoGAM has helped to protect millions of Rh-negative mothers and their babies.

Questions for your doctor

If you have additional questions about being Rh-negative or about RhoGAM, be sure to write them down so that you can ask your healthcare provider at your next visit.
Important Safety Information

RhoGAM® Ultra-Filtered PLUS [Rh₀(D) Immune Globulin (Human)] (300 µg) is indicated for the prevention of Rh immunization, including during and after pregnancy and other obstetrical conditions or incompatible transfusion of Rh-positive blood.

RhoGAM® is 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® is 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.

RhoGAM® contains a small quantity of IgA and physicians must weigh the benefit against the potential risks of hypersensitivity reactions. Hypersensitivity reactions include hives, generalized urticaria, tightness of the chest, wheezing, hypotension and anaphylaxis. Patients who receive RhoGAM® for Rh-incompatible transfusion should be monitored by clinical and laboratory means due to the risk of a hemolytic reaction.

For more information please see enclosed Full Prescribing Information or visit www.RhoGAM.com.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/Safety/MedWatch/ or call 1-800-FDA-1088
You can trust the safety of RhoGAM

RhoGAM has an excellent safety record. It is US manufactured and sourced from a known and trusted donor pool in Williamsville, NY.

- Since it was introduced in 1968, millions of women around the world have received RhoGAM and there have been no confirmed cases of viral transmission.

- The manufacturing process ensures the removal of viruses including hepatitis A virus and West Nile virus.

Important Safety Information

RhoGAM® Ultra-Filtered PLUS [Rh\(\text{D}\) Immune Globulin (Human)] (300 µg) is indicated for the prevention of Rh immunization, including during and after pregnancy and other obstetrical conditions or incompatible transfusion of Rh-positive blood.

RhoGAM® is 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.

For more information about RhoGAM visit www.RhoGAM.com


Rh(D) Immune Globulin (Human) 
RhGAM® Ultra-Filtered PLUS 
(MICRhoGAM) 
Rx Only

For Intramuscular Injection Only

MICRhoGAM® Ultra-Filtered PLUS (300 µg) (1500 IU)

Rx Only

INDICATIONS AND USAGE

For use in preventing Rh immunization.

- Pregnancy: Administration to Rh-negative women unless the father or baby are conclusively Rh-negative,
  e.g., delivery of an Rh-positive baby irrespective of the ABO groups of the mother and baby, any antepartum
  fetal-maternal hemorrhage (suspected or proved), actual or threatened pregnancy at any stage of gestation and
  eclopophy.

- Systemic reactions that include skin rash, body aches or a slight elevation
  in temperature. Patients should be observed for at least 20 minutes after
  administration. Severe anaphylactic reactions are extremely rare. (6)

- Anti-D formation is rarely reported after proper administration of RhoGAM. (6).

- Systemic allergic reactions that include skin rash, body aches or a slight elevation
  in temperature. Patients should be observed for at least 20 minutes after
  administration. Severe anaphylactic reactions are extremely rare. (6)

- Use of Plasma Derived Products

- Molecular biology and inactivation techniques during the manufacturing process. All of the
  presented above steps are designed to increase product safety by reducing the risk of pathogen
  disease (CJD) agent. The risk that such products will transmit an infectious agent has
  transmission. Despite these measures, such products can still potentially transmit
  infectious agents.

- Pregnancy and other obstetrical conditions.

- Patients treated for Rh-incompatible transfusion should be monitored by clinical
  and laboratory means for signs and symptoms of a hemolytic reaction. (5.1)

- MICRhoGAM Ultra-Filtered PLUS (50 µg) (250 IU)

- RhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtered PLUS

- MICRhoGAM® Ultra-Filtere...
The attending physician must weigh the benefit...

Although high doses of intravenous immune globulin containing IgA at levels of...

The immune response to the vaccination may be inhibited.12

Live vaccines should generally be delayed until 12 weeks after the final dose of immune...

Some babies born to women given RhIg Immune Globulin (Huminat) antigen-negative recipients were exposed to Rh-positive red blood cells in the circulation of the Rh-negative mother to cause a positive antibody screening test. This does not preclude further antenatal or postpartum prophylaxis.

Fetal-maternal hemolysis may cause fetal bleeding resulting in the mother, Latte in severe cases, hydrops fetalis. Antibody levels in the circulation of the Rh-negative mother to cause a positive antibody screening test.

The presence of polyvalent IgG and IgM antibodies against the Rh-negative antigen, carbohydrate identified on red cells from Rh-positive infants as the pRh(D) antigen, may be present in the mother.

Although RhGAM or MICRhoGAM should be administered.9

Immediate administration of Rho(D) Immune Globulin (Human) to Rh-negative mothers of Rh-positive or have received Rh-positive red blood cells may result in signs and symptoms of a hematologic reaction, including fever, back pain, nausea and vomiting, hypotension, and anaphylaxis.13 Rh-negative recipients may experience similar hematologic reactions. RhGAM and MICRhoGAM contain a small quantity of IgA (less than 15 µg per mL).

Because of the importance of rubella immunity among women of childbearing age, the postpartum vaccination of rubella-susceptible women with rubella or MMR vaccine...

The Rh-negative obstetrical patient may be exposed to red blood cells from her...

Virus Inactivation in Plasma

- EMC Encephalomyocarditis Virus, Model for Hepatitis A Virus
- HIV  Human Immunodeficiency Virus, Model for HIV-1 and 2 and Human T-cell Lymphoma Virus
- HBV  Hepatitis B Virus
- HCV  Hepatitis C Virus
- PRV  Pseudorabies Virus, Model for Herpes Virus
- Influenza Virus for EMC
- EME  Encephalomyocarditis Immunoglobulin
- HAV  Hepatitis A Virus
- hepatitis B surface antigen (HBsAg)
- N/A Not Applicable
- hepatitis B core antigen (HBcAg)
- N/A Not Applicable
- Hepatitis B core antibody (anti-HBc)
- N/A Not Applicable
- Hepatitis B surface antibody (anti-HBs) or immunoglobulin
- N/A Not Applicable
- non-hemolytic fever
- N/A Not Applicable
- RhGAM or MICRhoGAM Rho(D) Immune Globulin (Human) should only be administered to Rh-negative patients exposed or potentially exposed to Rh-positive red blood cells to prevent Rh sensitization.

The Rh-negative obstetrical patient may be exposed to red blood cells from her...

Pharmaceutical Properties

Pharmacokinetic studies after intramuscular injection were performed on 30 Rh-negative subjects receiving a single dose of 0.8 mL or 1.45 mL RhGAM. Plasma anti-D levels were monitored for thirteen weeks using a validated Automated Immunodiffusion assay (Coomassie capture). The following mean pharmacokinetic parameters were derived from data collected over the 13-week period: