

Rh₀(D) Immune Globulin (Human)

***RhoGAM*[®]**

Ultra-Filtered (300 µg)

***MICRhoGAM*[®]**

Ultra-Filtered (50 µg)

Rx Only

For Intramuscular Injection Only
Preservative-free, latex-free delivery system

DESCRIPTION

RhoGAM[®] and MICRhoGAM[®] Rh₀(D) Immune Globulin (Human) are sterile solutions containing IgG anti-D (anti-Rh) for use in preventing Rh immunization. They are manufactured from human plasma containing anti-D. A single dose of RhoGAM contains sufficient anti-D (approximately 300 µg)* to suppress the immune response to 15 mL (or less) of Rh-positive red blood cells.^{2,3} A single dose of MICRhoGAM contains sufficient anti-D (approximately 50 µg)* to suppress the immune response to 2.5 mL (or less) of Rh-positive red blood cells. The anti-D dose is measured by comparison to the RhoGAM in-house reference standard, the potency of which is established relative to the International Reference Preparation 68/419.

All donors are carefully screened by history and laboratory testing to reduce the risk of transmitting blood-borne pathogens from infected donors. Fractionation of the plasma is performed by a modification of the cold alcohol procedure that has been shown to significantly lower viral titers.⁴ Following fractionation, an additional viral-clearance filtration step is incorporated into the manufacturing process. This filtration step removes viruses via a size-exclusion mechanism utilizing a patented Viresolve[†] 180 ultrafiltration membrane with defined pore-size distribution of 12-18 nanometers. The ultrafiltration step utilizes tangential flow filtration to permit filtration of IgG while effectively retarding enveloped and non-enveloped viruses above the pore-size distribution cutoff. The filter is inert to the product. Non-enveloped viruses are known to be resistant to chemical and physical inactivation.^{5,6} Laboratory spiking studies have shown that the cumulative viral removal capability of the RhoGAM/MICRhoGAM manufacturing process exceeds 13 logs for human immunodeficiency virus (HIV). Clearance of model viruses for hepatitis C virus (HCV), hepatitis B virus (HBV) and parvovirus B19 (a non-enveloped virus) exceeds 11 logs.⁴ The donor selection process, the fractionation process and the Viresolve ultrafiltration step are designed to increase product safety by reducing the risk of transmission of enveloped and non-enveloped viruses. Rh₀(D) Immune Globulin (Human) intended for intramuscular use and prepared by cold alcohol fractionation has not been reported to transmit hepatitis or other infectious diseases.⁷

The safety of Rh₀(D) Immune Globulin (Human) has been further shown in an empirical study of viral marker rates in female blood donors in the United States.⁸ This study revealed that Rh-negative donors, of whom an estimated 55-60% had received Rh₀(D) Immune Globulin (Human) for pregnancy-related indications, had prevalence and incidence viral marker rates similar to those of Rh-positive female donors who had not received Rh₀(D) Immune Globulin (Human). Even after the fractionation and virus-filtration steps, there remains a risk of contracting blood-borne pathogens from a plasma-derived product.

The final product contains approximately 5 ± 1% gamma globulin, 2.9 mg/mL sodium chloride, 0.01% polysorbate 80 and 15 mg/mL glycine. Small amounts of IgA, typically less than 15 µg per dose, are present.³ The pH range is 6.20-6.55. The product contains no preservative and utilizes a latex-free delivery system.

*The anti-D content of RhoGAM/MICRhoGAM is expressed as µg per dose. It can be expressed as International Units (IU) per dose. The conversion factor is 1 µg = 5 IU.¹

[†]Viresolve is a trademark of Millipore Corporation.

CLINICAL PHARMACOLOGY**Mechanism of Action**

RhoGAM® and MICRhoGAM® act by suppressing the immune response of Rh-negative individuals to Rh-positive red blood cells. The mechanism of action is unknown. RhoGAM, MICRhoGAM and other Rh₀(D) Immune Globulin (Human) products are not effective in altering the course or consequences of Rh immunization once it has occurred.

Obstetrical Use

The Rh-negative obstetrical patient may be exposed to red blood cells from her Rh-positive fetus during the normal course of pregnancy or after obstetrical procedures or abdominal trauma. Clinical studies have proven that the incidence of Rh immunization as a result of pregnancy was reduced to 1-2% from 12-13% when RhoGAM was given within 72 hours following delivery.^{10,11} Antepartum administration of Rh immune globulin at 28 weeks, as well as within 72 hours of delivery, has been shown to reduce the Rh immunization rate to about 0.1-0.2%.^{12,13}

Clinical studies demonstrated that administration of MICRhoGAM within three hours following abortion was 100% effective in preventing Rh immunization.¹⁴

Use after Rh Incompatible Transfusion

An Rh-negative individual transfused with one unit of Rh-positive red blood cells has about an 80% likelihood of producing anti-D.³ However, Rh immunization can occur after exposure to < 1 mL of Rh-positive red blood cells. Protection from Rh immunization is accomplished by administering the appropriate dose of RhoGAM or MICRhoGAM, which is $\geq 20 \mu\text{g}$ per mL of Rh-positive red blood cells, within 72 hours of transfusion of incompatible red cells.^{2,15} (See **DOSAGE AND ADMINISTRATION** section.)

Pharmacokinetic Properties

Pharmacokinetic studies after intramuscular injection were performed on eight Rh-negative subjects.¹⁶ Six subjects received a single dose (300 μg) of RhoGAM, while two subjects received four doses (1200 μg). Plasma anti-D levels were monitored for four months using a validated method with sensitivity of approximately 1 ng/mL. The parameters measured and/or calculated included the following:

C_{max} = maximum plasma concentration obtained (ng/mL)

T_{max} = time to attain C_{max} (days)

$T_{1/2}$ = elimination half-life (days)

V_d = volume of distribution (liters)

Mean Pharmacokinetic Parameters for RhoGAM

Parameter	Single Dose (n = 6)	Four Doses (n = 2)	Dose Ratio (1/4)
C_{max}	37.1	146.3	0.253
T_{max}	5	5	0.999
$T_{1/2}$	24.2	27.0	0.933
V_d	8.59	8.16	1.053

INDICATIONS AND USAGE**Pregnancy and Other Obstetrical Conditions in Rh-Negative Women, Unless the Father or Baby are Conclusively Rh Negative**

- Pregnancy/delivery of an Rh-positive baby irrespective of the ABO groups of the mother and baby
- Abortion/threatened abortion at any stage of gestation
- Ectopic pregnancy
- Antepartum fetal-maternal hemorrhage (suspected or proven) resulting from antepartum hemorrhage (e.g., placenta previa), amniocentesis, chorionic villus sampling, percutaneous umbilical blood sampling, other obstetrical manipulative procedure (e.g., version) or abdominal trauma
- Transfusion of Rh incompatible blood or blood products

Transfusion

- Prevention of Rh immunization in any Rh-negative person after incompatible transfusion of Rh-positive blood or blood products (e.g., red cells, platelet concentrates, granulocyte concentrates)

CONTRAINDICATIONS

Individuals known to have had an anaphylactic or severe systemic reaction to human globulin should not receive RhoGAM[®], MICRhoGAM[®] or any other Rh₀(D) Immune Globulin (Human).

WARNINGS

RhoGAM[®] and MICRhoGAM[®] are made from human plasma. Because these 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. The risk that such products will transmit an infectious agent has been reduced by screening plasma donors for prior exposure to certain viruses, by testing for the presence of certain current virus infections and by removing certain viruses during the manufacturing process. Following fractionation, an additional viral-clearance filtration step is incorporated into the manufacturing process. This filtration step removes viruses via a size-exclusion mechanism utilizing a patented Viresolve 180 ultrafiltration membrane with a defined pore-size distribution of 12-18 nanometers. The filter is inert to the product. This virus removal process has been shown in laboratory spiking studies to reduce the levels of some viruses ranging from 18-200 nanometers in size, including enveloped viruses as well as non-enveloped viruses.⁴ All of the above steps are designed to increase product safety by reducing the risk of transmission of lipid-enveloped and non-lipid-enveloped viruses. Despite these measures, such products can still potentially transmit disease. There is also the possibility that unknown infectious agents may be present in such products. ALL infections thought by a physician possibly to have been transmitted by these products should be reported by the physician or other healthcare provider in the United States to Ortho-Clinical Diagnostics, Inc. at 1-800-421-3311. Outside the United States, the company distributing these products should be contacted. The physician should discuss the risks and benefits of these products with the patient. RhoGAM and MICRhoGAM are manufactured and distributed by Ortho-Clinical Diagnostics, Inc., Raritan, NJ 08869.

PRECAUTIONS

For intramuscular use only. Do not inject RhoGAM[®] or MICRhoGAM[®] intravenously. In the case of postpartum use, the product is intended for maternal administration. Do not inject the newborn infant.

Patients should be observed for at least 20 minutes after administration.

Allergic responses to RhoGAM or MICRhoGAM may occur. Patients should be informed of the early signs of hypersensitivity reactions, including hives, generalized urticaria, tightness of the chest, wheezing, hypotension and anaphylaxis. The treatment depends upon the nature and severity of the reaction.

RhoGAM and MICRhoGAM contain a small quantity of IgA (less than 15 µg per dose).⁹ Although high doses of intravenous immunoglobulin containing IgA at levels of 270-720 µg/mL have been given without incident during treatment of patients with high-titered antibodies to IgA,¹⁷ the attending physician must weigh the benefit against the potential risks of hypersensitivity reactions.

The presence of passively acquired anti-D in the maternal serum may cause a positive antibody screening test. This does not preclude further antepartum or postpartum prophylaxis.

Some babies born of women given Rh₀(D) Immune Globulin (Human) antepartum have weakly positive direct antiglobulin (Coombs) tests at birth.

Fetal-maternal hemorrhage may cause false blood typing results in the mother. Late in pregnancy or following delivery, there may be sufficient fetal Rh-positive red blood cells in the circulation of the Rh-negative mother to cause a positive antiglobulin test for weak D (D^w). When there is any doubt as to the patient's Rh type, RhoGAM or MICRhoGAM should be administered.

Pregnancy Category C

Animal reproduction studies have not been conducted with RhoGAM or MICRhoGAM. The available evidence suggests that Rh₀(D) Immune Globulin (Human) does not harm the fetus or affect future pregnancies or the reproduction capacity of the maternal recipient.^{18,19}

ADVERSE REACTIONS

Adverse experience (AE) complaints related to RhoGAM® Ultra-Filtered and MICRhoGAM® Ultra-Filtered are received at a rate of approximately one complaint per 60,000 doses distributed for use.²⁰ These AE complaints are split between reports of anti-D formation despite RhoGAM or MICRhoGAM administration and reports of local reactions at the site of administration.

Local AE reactions include swelling, induration, redness and mild pain at the site of injection, and a small number of patients have noted a slight elevation in temperature. Rarely, these reactions have been treated with antihistamines or corticosteroids. Systemic reactions to RhoGAM or MICRhoGAM are extremely rare. There have been no reported fatalities due to anaphylaxis or any other cause related to RhoGAM or MICRhoGAM administration.

As with any Rh₀(D) Immune Globulin (Human), administration to patients who have received Rh-positive red blood cells may result in signs and symptoms of a hemolytic reaction, including fever, back pain, nausea and vomiting, hypo- or hypertension, hemoglobinuria/emia, elevated bilirubin and creatinine and decreased haptoglobin.

DOSAGE AND ADMINISTRATION

For intramuscular use only. Do not inject RhoGAM® or MICRhoGAM® intravenously. In the case of postpartum use, the product is intended for maternal administration. Do not inject the newborn infant.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration.

A single dose (approximately 50 µg)* is contained in each prefilled syringe of MICRhoGAM. This dose will suppress the immune response to 2.5 mL of Rh-positive red blood cells. MICRhoGAM is therefore indicated within 72 hours after termination of pregnancy up to and including 12 weeks' gestation. At or beyond 13 weeks' gestation, RhoGAM should be administered instead of MICRhoGAM.

A single dose (approximately 300 µg)* is contained in each prefilled syringe of RhoGAM. This is the usual dose for the indications associated with pregnancy unless there is clinical or laboratory evidence of a fetal-maternal hemorrhage (FMH) in excess of 15 mL of Rh-positive red blood cells. RhoGAM should be administered within 72 hours of known or suspected exposure to Rh-positive red blood cells. The indications and recommended dosage for RhoGAM and MICRhoGAM are summarized in the following table.

Indications and Recommended Dosage

Indication	Indicated Dose^a (approximately)
Postpartum (if the newborn is Rh-positive)	300 µg ^b
Antepartum: Prophylaxis at 26 to 28 weeks' gestation ^c	300 µg
Antepartum: Amniocentesis, chorionic villus sampling (CVS) and percutaneous umbilical blood sampling (PUBS)	300 µg
Antepartum: Abdominal trauma or obstetrical manipulation	300 µg
Antepartum: Ectopic pregnancy ^d	300 µg
Antepartum: Abortion or threatened abortion at any stage of gestation with continuation of pregnancy ^d	300 µg
Transfusion of Rh-incompatible blood or blood products ^d	300 µg

^a Additional doses of RhoGAM are indicated when the patient has been exposed to > 15 mL of Rh-positive red blood cells. This may be determined by use of qualitative or quantitative tests for FMH (see below).

^b See **DESCRIPTION** section.

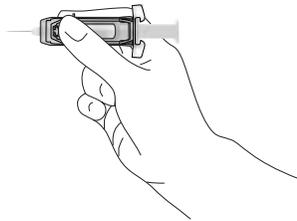
^c If antepartum prophylaxis is indicated, it is essential that the mother receive a postpartum dose if the infant is Rh-positive.

^d If abortion or termination of pregnancy occurs up to and including 12 weeks' gestation, or less than 2.5 mL of Rh-incompatible red blood cells were administered, a single dose of MICRhoGAM Rh₀(D) Immune Globulin (Human) (approximately 50 µg)* may be used instead of RhoGAM.

If RhoGAM is administered for one of the above indications early in pregnancy (before 26 to 28 weeks), there is an obligation to maintain a level of passively acquired anti-D by administration of RhoGAM at 12-week intervals. RhoGAM should be administered within 72 hours of delivery or exposure to Rh-positive red blood cells. There is little information concerning the effectiveness of Rh Immune Globulin when given beyond this 72-hour period. In one study, Rh Immune Globulin provided protection against Rh immunization in about 50% of subjects when given 13 days after exposure to Rh-positive cells.²¹ If delivery occurs within three weeks after the last antepartum dose, the postpartum dose may be withheld, but a test for FMH should be performed to determine if exposure to > 15 mL of red cells has occurred.²²

Multiple doses of RhoGAM are required if an FMH exceeds 15 mL, an event that is possible but unlikely prior to the third trimester of pregnancy and is most likely at delivery. Patients known or suspected to be at increased risk of FMH should be tested for FMH by qualitative or quantitative methods.²³ In efficacy studies, RhoGAM was shown to suppress Rh immunization in all subjects when given at a dose of $\geq 20 \mu\text{g}$ per mL of Rh-positive red blood cells.³ Thus, a single dose of RhoGAM will suppress the immune response after exposure to ≤ 15 mL of Rh-positive red blood cells. However, in clinical practice, laboratory methods used to determine the amount of exposure (volume of transfusion or FMH) to Rh-positive red blood cells are imprecise.^{24,25} Therefore, administration of more than 20 μg of RhoGAM per mL of Rh-positive red blood cells should be considered whenever a large FMH or red cell exposure is suspected or documented.²⁵

When multiple doses are required, consult your pharmacy for pooling directions. Multiple doses may be administered at the same time or at spaced intervals, as long as the total dose is administered within three days of exposure.



Administer injection.

Administer injection per standard protocol.

Note: When administering an intramuscular injection, place fingers in contact with syringe barrel through windows in shield to prevent possible premature activation of safety guard.

Slide safety guard over needle.

After injection, use free hand to slide safety guard over needle. An audible "click" indicates proper activation.

Keep hands behind needle at all times.



Overdosage

Patients who receive RhoGAM or MICRhoGAM for Rh-incompatible transfusion should be monitored by clinical and laboratory means due to the risk of a hemolytic reaction.

HOW SUPPLIED

RhoGAM® is available in packages containing:

- 5 prefilled single-dose syringes of RhoGAM (Product Code 780710) NDC 0562-7807-06
 - 5 package inserts
 - 5 control forms
 - 5 patient identification cards
- and
- 25 prefilled single-dose syringes of RhoGAM (Product Code 780715) NDC 0562-7807-26
 - 25 package inserts
 - 25 control forms
 - 25 patient identification cards

MICRhoGAM® is available in packages containing:

- 5 prefilled single-dose syringes of MICRhoGAM (Product Code 780810) NDC 0562-7808-06
 - 5 package inserts
 - 5 control forms
 - 5 patient identification cards
- and
- 25 prefilled single-dose syringes of MICRhoGAM (Product Code 780815) NDC 0562-7808-26
 - 25 package inserts
 - 25 control forms
 - 25 patient identification cards

STORAGE

Store at 2 to 8°C. Do not store frozen.

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SUMMARY OF REVISIONS

Printing specification change only. No change to directions for use.



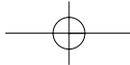
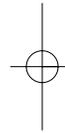
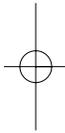
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U.S. LICENSE 1236

Raritan, New Jersey 08869

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U.S. Patent 3,449,314

Revised September 2001
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CONTROL FORM RhogAM® and MICRhogAM® Rh₀(D) Immune Globulin (Human) Ultra-Filtered

Hospital _____

ATTENTION LABORATORY

Patient's Name _____

Hospital No. _____ Room No. _____

Patient is Rh negative _____ Date _____

Baby's Rh₀(D) type is positive or unknown _____ Date _____

FMH screening test performed, if indicated _____ Date _____

LOT NO. OF RhogAM or MICRhogAM ISSUED _____ EXP. DATE _____
(circle product administered)

Tech. _____

ATTENTION OBSTETRICAL SERVICE

IMPORTANT

1. Establish patient identification before injecting this single dose of RhogAM or MICRhogAM intramuscularly.
2. Verify the lot number and expiration date of RhogAM or MICRhogAM recorded on this form with the lot number and expiration date printed on the prefilled syringe of RhogAM or MICRhogAM.
3. Retain this form for verification of administration of RhogAM or MICRhogAM.

Date RhogAM or MICRhogAM injected _____

ANTEPARTUM _____ POSTPARTUM _____

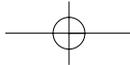
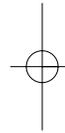
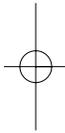
- After amniocentesis Abortion
 28-week prophylaxis Full-term delivery
 Other indication

(specify) _____ Delivered/Terminated _____ Date _____

Gestational age _____

Attending physician _____

Part 1



CONTROL FORM RhogAM® and MICRhogAM® Rh₀(D) Immune Globulin (Human) Ultra-Filtered

Hospital _____

ATTENTION LABORATORY

Patient's Name _____

Hospital No. _____ Room No. _____

Patient is Rh negative _____ Date _____

Baby's Rh₀(D) type is positive or unknown _____ Date _____

FMH screening test performed, if indicated _____ Date _____

LOT NO. OF RhogAM or MICRhogAM ISSUED _____ EXP. DATE _____
(circle product administered)

Tech. _____

ATTENTION OBSTETRICAL SERVICE

IMPORTANT

1. Establish patient identification before injecting this single dose of RhogAM or MICRhogAM intramuscularly.
2. Verify the lot number and expiration date of RhogAM or MICRhogAM recorded on this form with the lot number and expiration date printed on the prefilled syringe of RhogAM or MICRhogAM.
3. Retain this form for verification of administration of RhogAM or MICRhogAM.

Date RhogAM or MICRhogAM injected _____

ANTEPARTUM

POSTPARTUM

After amniocentesis

Abortion

28-week prophylaxis

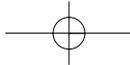
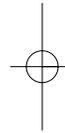
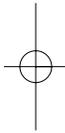
Full-term delivery

Other indication

(specify) _____ Delivered/Terminated _____

Gestational age _____ Date _____

Attending physician _____



CONTROL FORM RhogAM® and MICRhogAM® Rh₀(D) Immune Globulin (Human) Ultra-Filtered

Hospital _____

ATTENTION LABORATORY

Patient's Name _____

Hospital No. _____ Room No. _____

Patient is Rh negative _____ Date _____

Baby's Rh₀(D) type is positive or unknown _____ Date _____

FMH screening test performed, if indicated _____ Date _____

LOT NO. OF RhogAM or MICRhogAM ISSUED (circle product administered) _____ EXP. DATE _____

Tech. _____

ATTENTION OBSTETRICAL SERVICE

IMPORTANT

1. Establish patient identification before injecting this single dose of RhogAM or MICRhogAM intramuscularly.
2. Verify the lot number and expiration date of RhogAM or MICRhogAM recorded on this form with the lot number and expiration date printed on the prefilled syringe of RhogAM or MICRhogAM.
3. Retain this form for verification of administration of RhogAM or MICRhogAM.

Date RhogAM or MICRhogAM injected _____

ANTEPARTUM _____ POSTPARTUM _____

After amniocentesis Abortion

28-week prophylaxis Full-term delivery

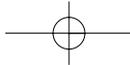
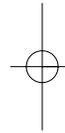
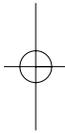
Other indication

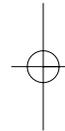
(specify) _____ Delivered/Terminated _____ Date _____

Gestational age _____

Attending physician _____

Part 3 - RETURN TO HOSPITAL LABORATORY





PATIENT IDENTIFICATION CARD

Name _____

Address _____

I AM Rh NEGATIVE. I have received a protective injection of RhoGAM® or MICRhoGAM® Rh₀(D) Immune Globulin (Human) Ultra-Filtered.
IMPORTANT: Anti-Rh antibody (also called anti-D) will be present in my blood for several weeks after the injection, and may be detectable by laboratory testing. The presence of this passive anti-Rh antibody does not disqualify me from receiving additional injections of RhoGAM or MICRhoGAM as indicated and prescribed by my physician.

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Rh₀(D) Immune Globulin (Human)

RhoGAM[®] and MICRhoGAM[®]

Ultra-Filtered

This 3-part form contains:

- Directions for Use
- Patient Control Form
- Patient Identification Card



Ortho-Clinical Diagnostics, Inc.

a *Johnson & Johnson* company

Raritan, New Jersey 08869

631209713

Date of Injection of RhoGAM or MICRhoGAM

(circle product administered)

Lot No.

Exp. Date

Injection was:

- at pregnancy termination
- during pregnancy
- after delivery

Attending Physician

Physician's Telephone Number