Rhø(D) Immune Globulin (Human)
RhoGAM®
MICRhøGAM®
Rx Only
For Intramuscular Injection Only
Preservative-free, latex-free delivery system

DESCRIPTION
RhoGAM® and MICRhøGAM® Rh(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 sufficient anti-D (approximately 50 µg)* to suppress the immune response to 2.5 mL of Rh-positive red blood cells. A single dose of MICRhøGAM contains sufficient anti-D (approximately 50 µg)* to suppress the immune response to 2.5 mL of Rh-positive red blood cells. The anti-D dose is measured by comparison to the RhGAM in-house reference standard, the potency of which is established relative to the International Reference Preparation 68/19. The final product contains approximately 5 ± 1% gamma globulin, 2.9 mg/mL sodium chloride, 0.01% polysorbate 80 and 15 mg/mL glycerine. Small amounts of IgA, typically less than 15 µg per dose, are present. 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/MICRhøGAM is expressed as µg per dose. It can be expressed as International Units (IU) per dose. The conversion factor is 1 µg = 5 IU.

CLINICAL PHARMACOLOGY

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 is about 1% after spontaneous or induced abortion up to 12-13% when RhoGAM was given within 72 hours following delivery. Antepartum administration of Rh immune globulin in the first 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%. Clinical studies demonstrated that administration of MICRhøGAM within three hours following abortion is 100% effective in preventing Rh immunization.

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. 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 MICRhøGAM, which is expressed as International Units (IU) per dose, within 72 hours of transfusion of incompatible red blood cells. (See DOSAGE AND ADMINISTRATION section.)

INDICATIONS AND USAGE
Pregnancy and Other Obstetrical Conditions in Rh-Negative Women, Unless the Father or Baby are Clinically Resh 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), amnionitis, chiorionic villus sampling, pregestational 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, plasma substitute concentrates)

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

WARNINGS
RhoGAM® and MICRhøGAM® 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 viral particles. Following further steps, 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 inset to the product. This virus removal process has been demonstrated by a study comparing the levels of some viruses ranging from 18-200 nanometers in size, including enveloped viruses as well as non-enveloped viruses. 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 to be transmitted by these products should be reported to the physician or other healthcare provider in the United States to Ortho-Clarkovs, Inc., at 1-800-421-3311. Outside the United States, the company designated for this purpose should be the physician who diagnosed the infection or the patient's pediatrician who will discuss the risks and benefits of these products with the patient. RhoGAM and MICRhøGAM are manufactured and distributed by Ortho-Clarkovs, Inc., Raritan, NJ 08869.

PRECAUTIONS
For intramuscular use only. Do not inject RhoGAM® or MICRhøGAM® 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 MICRhøGAM 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 MICRhøGAM contain a small quantity of IgA (less than 15 µg per dose). Although high doses of intravenous immunoglobulin containing IgA at levels of 270-720 µg/mL have been given without anaphylactic 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 Rh(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 Rh-positive red blood cells in the circulation of the Rh-negative mother to cause a positive antigen test for weak D (DP). When there is any doubt as to whether the patient's Rh type, RhoGAM or MICRhøGAM should be administered.

Pregnancy Category C
Animal reproduction studies have not been conducted with RhoGAM or MICRhøGAM, which is expressed as International Units (IU) per dose. However, in clinical practice, laboratory methods used to determine the amount of exposure (volume of transfusion or Rh-negative red blood cells) are imprecise. Therefore, administration of more than 20 µg of RhGAM per mL of Rh-positive red blood cells should be considered whenever a large FMH or cell exposure is suspected or documented. When multiple doses are required, consult your pharmacy for pooling directions. Multiple doses required may be administered at the same time or at spaced intervals, as long as the total dose is administered within three days of exposure.

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

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

NOTE: For complete prescribing information, see package insert.

Ortho-Clarkovs, Raritan, New Jersey 08869

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Indications and Recommended Dosage

<table>
<thead>
<tr>
<th>Indication</th>
<th>Recommended Dose (µg)</th>
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<tbody>
<tr>
<td>Postpartum (if the newborn is Rh-positive)</td>
<td>300 µg</td>
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<tr>
<td>Antepartum: Prophylaxis at 26 to 28 weeks’ gestation*</td>
<td>300 µg</td>
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<tr>
<td>Antepartum: Annoincentesis, chorionic villus sampling (CVS) and percutaneous umbilical blood sampling (PUBS)</td>
<td>300 µg</td>
</tr>
<tr>
<td>Antepartum: Abdominal trauma or obstetrical manipulation</td>
<td>300 µg</td>
</tr>
<tr>
<td>Antepartum: Ectopic pregnancy*</td>
<td>300 µg</td>
</tr>
<tr>
<td>Antepartum: Abortion or threatened abortion at any stage of gestation with continuation of pregnancy</td>
<td>300 µg</td>
</tr>
</tbody>
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Indications:
- Transfusion of Rh-incompatible blood or blood products

* 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 quantitative or qualitative tests for FMH (see below).

Additional dose (approximately)
- 300 µg