

# Guidelines for the use of Rh (D) immunoglobulin

in pregnant women with Rh (D) negative blood group, and no pre-existing anti-D antibodies<sup>1</sup>

- Rh (D) immunoglobulin should be administered as soon as possible after the sensitising event, but always within 72 hrs for successful immunoprophylaxis.<sup>1,2</sup>
- If Rh (D) immunoglobulin has not been administered within 72 hrs, a dose offered within 10 days may provide protection.<sup>1</sup>
- To avoid wastage, Rh (D) immunoglobulin should not be given to women with preformed anti-D antibodies, except where the preformed anti-D is due to the antenatal administration of Rh (D) immunoglobulin.<sup>1</sup>
- Original studies have shown that 100 IU of Rh (D) immunoglobulin is sufficient to protect against a Fetomaternal Haemorrhage (FMH) of 1.0 mL of fetal red cells (2 mL whole blood).<sup>1</sup> For example, Rh (D) immunoglobulin 625 IU is sufficient to protect against a FMH of 6 mL of fetal red cells (12 mL of whole blood).
- Quantify the magnitude of the FMH following a sensitising event (including delivery) to ensure an adequate dose of Rh (D) immunoglobulin is offered, as more than one dose may be required.<sup>1</sup>

For each sensitising event eg. normal delivery, miscarriage, termination of pregnancy, ectopic pregnancy, chorionic villus sampling, amniocentesis, abdominal trauma, antepartum haemorrhage, or external cephalic version. <sup>1,2</sup>			
Week 1 to Week 12 (first trimester)		Beyond Week 12 (second & third trimester)	Postpartum
Rh (D) Immunoglobulin-VF (Single pregnancy)	Rh (D) Immunoglobulin-VF (Multiple pregnancy eg. twins)	Rh (D) Immunoglobulin-VF	Rh (D) Immunoglobulin-VF
250 IU	625 IU	625 IU	625 IU

  

Routine prophylaxis is recommended for all Rh (D) negative pregnant women.	Rh (D) Immunoglobulin-VF
Administer at Week 28 and Week 34	625 IU  The doses at 28 & 34 weeks are given in ADDITION to any doses given for sensitising events.

Rh (D) Immunoglobulin-VF is administered by intramuscular injection only.<sup>2</sup>

- Tests to assess the volume of FMH include, but are not limited to, the Kleihauer acid elution test and flow cytometry.<sup>1</sup>
- The majority of fetal bleeds are less than 5 mL of red blood cells
  - in about 74% of cases, FMH is < 0.05 mL whole blood mL<sup>3,4</sup>
  - in about 8% of cases, FMH is > 0.4 mL whole blood<sup>3,4</sup>
  - in about 4% of cases, FMH is > 1 mL whole blood<sup>3,4</sup>
  - in 0.3-0.6% of cases, FMH is ≥ 30 mL<sup>3,4</sup>
- Approximately 15% of pregnant women will be Rh (D) negative, and their babies (if Rh (D) positive) may be at risk of developing Haemolytic Disease of the Newborn (HDN) due to Rh (D) incompatibility.<sup>5</sup>
- Antibody formation occurs during pregnancy in about 1-1.5% of Rh (D) negative women carrying a Rh (D) positive infant, despite use of postnatal prophylaxis. The rate of antibody formation can be reduced to 0.2% or less by the administration of Rh (D) immunoglobulin during pregnancy, at 28 weeks and 34 weeks (antenatal prophylaxis), as well as after delivery.<sup>4,6</sup>

In some circumstances, access to an intravenous Rh (D) immunoglobulin preparation may be warranted. A quantity of intravenous Rh (D) immunoglobulin will be available for this purpose. Contact ARCBS for further information.

The batch number of every vial of human immunoglobulin administered must be recorded in the patient's medical history and in accordance with other legal statutory requirements.<sup>2</sup>

#### References:

1. National Blood Authority Guidelines on the prophylactic use of Rh (D) immunoglobulin (anti-D) in obstetrics. June 2003.
2. Rh (D) Immunoglobulin-VF Approved Product Information amended 07 December 2007.
3. Sebring ES, Polesky HF. Fetomaternal hemorrhage: Incidence, risk factors, time of occurrence, and clinical effects. *Transfusion* 1990;30(4):344-357.
4. Zipursky A, Rh hemolytic disease of the newborn - the disease eradicated by immunology. *Clinical obstetrics and gynecology*; Vol 20, Sept 1977.
5. Australian & New Zealand Society of Blood Transfusion (ANZSBT). *Topics in transfusion medicine*. Vol 10, No.1; May 2003.
6. Crowther CA, Middleton P. Anti-D administration in pregnancy for preventing Rhesus alloimmunisation. *Cochrane Database of Systematic Reviews*, Issue 2; 1999.

PBS Information: This product is not listed on the PBS. This product is funded under arrangements implemented by the National Blood Authority. Please refer to the National Blood Authority for details.

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## Before prescribing, please review Product Information available on request from CSL Biotherapies

#### Minimum Product Information

**Rh (D) Immunoglobulin – VF** (Human Anti-D Rh<sub>0</sub> Immunoglobulin)

**Indications:** The prevention of Rh sensitisation in Rh(D) negative females at or below child bearing age. **Contraindications:** Individuals who are Rh(D) positive or D<sup>u</sup> positive; Rh negative and D<sup>u</sup> negative individuals previously sensitised to the Rh(D) antigen; individuals with IgA deficiency; individuals with coagulation disorders that would contraindicate intramuscular injections. **Precautions:** Rh(D) IMMUNOGLOBULIN-VF must not be administered intravenously. It should not be given to Rh(D) positive infants. Rh(D) IMMUNOGLOBULIN-VF should be given with caution to patients with a history of prior systemic allergic reactions following the administration of human immunoglobulin preparations. Rh(D) IMMUNOGLOBULIN-VF is made from human plasma. Products made from human plasma may contain infectious agents, such as viruses and theoretically Creutzfeldt-Jakob Disease (CJD) agents, that can cause disease. The risk that such products will transmit an infectious agent has been reduced by screening plasma donors, and by dedicated virus removal and inactivation procedures included in the manufacturing process. Despite these measures, such products may still potentially transmit disease. Vaccination for patients in receipt of medicinal products from human plasma should be considered where appropriate. **Interactions:** Rh(D) IMMUNOGLOBULIN-VF may interfere with serological testing and may affect the response to live, attenuated vaccines. For all precautions and interactions review approved PI. **Adverse Effects:** Local tenderness, erythema and stiffness at the injection site. For less common reactions review approved PI. **Dosage & Administration:** 250 IU after sensitising events during the first trimester of pregnancy; this should be increased to 625 IU for twin and multiple pregnancies. 625 IU after sensitising events beyond the first trimester. For mismatched transfusions or large foeto-maternal bleeds 100 IU Rh(D) IMMUNOGLOBULIN-VF should be administered for each 1.0 mL of Rh(D) positive red cells. The dose should be given as early as possible and within 72 hours of exposure. Rh(D) IMMUNOGLOBULIN-VF must be given by intramuscular injection. Contains no antimicrobial agent, use immediately after opening. Based on Rh(D) IMMUNOGLOBULIN-VF Approved Product Information amended 7 December 2007.

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