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## Guideline for the prophylactic use of Rh D immunoglobulin in pregnancy care

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| **What you need to know** |
| The ERG **recommends** the testing of maternal blood to determine fetal *RHD* genotype in all Rh D negative pregnant women to enable targeted antenatal Rh D immunoprophylaxis.a See R9  a The ERG’s recommendation on the use of NIPT for fetal *RHD* is not a policy statement on funding and supply arrangements for the national provisions of NIPT for blood group genotyping to determine the Rh D status of the fetus. |
| The ERG **recommends** that antenatal Rh D immunoprophylaxis in Rh D negative pregnant women with no preformed anti-D antibodies be targeted to those predicted to be carrying an Rh D positive fetus, based on NIPT for fetal *RHD*. This applies to both routine and sensitising event immunoprophylaxis, if the result of fetal *RHD* genotyping is available. See R6 |
| The ERG **recommends** that administration of Rh D immunoglobulin 625 IU at 28 and 34 weeks of pregnancy continue in Rh D negative pregnant women with no preformed anti-D antibodies unless NIPT for fetal RHD has predicted that they are not carrying an Rh D positive fetus. The ERG does not currently suggest changing to a single dose of Rh D immunoglobulin 1500 IU. See R2 |
| After the following sensitising events in the first 12 weeks of singleton or multiple pregnancy: miscarriage, termination of pregnancy (after 10 weeks gestation), ectopic pregnancy, molar pregnancy and chorionic villus sampling, the ERG **recommends** that a dose of Rh D immunoglobulin 250 IU be given to all Rh D negative women with no preformed anti-D antibodies to prevent Rh D alloimmunisation. See R3 |
| In the setting of termination of pregnancy before 10 weeks of gestation there is **insufficient evidence to suggest** the routine use of Rh D immunoglobulin. See R4 |
| The ERG currently **recommends** that postnatal Rh D immunoprophylaxis (Rh D immunoglobulin 625 IU) continue to be administered to all Rh D negative women with no preformed anti-D antibodies who have a baby who is predicted to be Rh D positive based on NIPT for fetal RHD, or cord blood or neonatal Rh D typing. The cord blood or neonatal testing should be performed regardless of the results of NIPT for fetal RHD, but need not delay administration of Rh D immunoprophylaxis when the fetus has been shown to be RHD positive by NIPT testing. If the baby is Rh D positive, administer Rh D immunoglobulin even if the NIPT predicted an Rh D negative baby. See R8 |

The *Guideline for the prophylactic use of Rh D immunoglobulin in pregnancy care* was published online in 2021 and republished in 2024 on MAGICapp. The guideline has recommendations and expert opinion points for health professionals on the appropriate use and timing of:

* pathology tests to identify maternal and fetal Rh D status
* prophylactic Rh D immunoglobulin in Rh D negative pregnant women

The guideline was developed by an expert reference group (ERG) using GRADE methodology. This summary contains:

* the guideline recommendations (R) and expert opinion points (EOP) (see Recommendation definitions)
* a summary table on use and timing of pathology testing
* routine immunoprophylaxis summary table
* summary table of sensitising event immunoprophylaxis
* two care pathways that outline the timing of pathology testing and administration of Rh D immunoglobulin

The guideline was a joint project between the Royal Australian and New Zealand College of Obstetricians and Gynaecologists and the National Blood Authority (NBA). The NBA provided project management and funded all goods and services associated with the guidelines development. The recommendations and expert opinion points were not influenced by the views or interests of the NBA. View the full guideline for more information [www.nba.gov.au/](http://www.nba.gov.au/)anti-d-0. Summary last updated {enter date]

**Recommendation definitions:**

**Strong recommendation (for)**: the ERG is confident that the desirable effects of an intervention outweigh its undesirable effects.

**Weak recommendation (for)**: the desirable effects probably outweigh the undesirable effects, but appreciable uncertainty exists.

Recommendation is influenced by a woman’s values, resources available and/or setting.

**Weak recommendation (against)**: the undesirable effects probably outweigh the desirable effects, but appreciable uncertainty exists. Recommendation is influenced by a woman’s values, resources available and/or setting.

**Expert opinion point:** developed by consensus where there was insufficient quantity or certainty of evidence, but it was considered important to offer guidance.

| Recommendations and expert opionion points | |
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| **Blood group and antibody screening in all pregnant women** | |
| **EOP1** | All women should have an ABO / Rh D type and antibody screen performed no later than 10 weeks gestation. Rh D positive pregnant women do not require Rh D immunoglobulin.\*  \* If the mother has a weak or variant Rh D type, consult a haematopathologist in regard to interpretation of results and management. |
| **EOP2** | If antibody screening identifies anti-D in an Rh D negative pregnant woman, consideration of clinical history and laboratory findings is required to determine whether the anti-D is likely to be preformed (due to sensitisation) or passive (due to administration of Rh D immunoglobulin in the past 12 weeks).\* In cases of likely preformed anti-D antibodies, seek specialist obstetric advice, manage as Rh D sensitised and consider NIPT for fetal Rh D status.  \* See EOP3 |
| **EOP3** | Rh D immunoglobulin should not be given to Rh D negative pregnant women with preformed anti-D antibodies. However, if it is unclear whether the anti-D detected in the mother’s blood is preformed (due to sensitisation) or passive (due to administration of Rh D immunoglobulin in the past 12 weeks), the treating clinician should be consulted. If there is continuing doubt, Rh D immunoglobulin should be administered. |
| **Non-invasive prenatal testing for fetal *RHD* in all Rh D negative pregnant women** | |
| **R9** | The ERG **recommends** the testing of maternal blood to determine fetal *RHD* genotype in all Rh D negative pregnant women to enable targeted antenatal Rh D immunoprophylaxis.\* (*Strong recommendation, high certainty of evidence about the accuracy of the test*)  \*The ERG’s recommendation on the use of NIPT for fetal *RHD* is not a policy statement on funding and supply arrangements for the national provisions of NIPT for blood group genotyping to determine the Rh D status of the fetus.  As of February 2024, NIPT for fetal RHD status is not widely available in Australia. Universal Rh D immunoprophylaxis should be maintained until NIPT is widely accessible.  Further details are provided on the NBA website |
| **R10** | The ERG **recommends** that test sensitivity be at least 99% in order to minimise the number of Rh D positive fetuses being missed by the test. (*Strong recommendation, high certainty of evidence about the accuracy of the test*) |
| **R11** | The ERG **recommends** NIPT for fetal *RHD* from 11+0 weeks of pregnancy because of higher test accuracy than at earlier weeks. (*Strong recommendation, high certainty of evidence about the accuracy of the test*) |
| **Targeted immunoprophylaxis in Rh D negative pregnant women** | |
| **R6** | The ERG **recommends** that antenatal Rh D immunoprophylaxis in Rh D negative pregnant women with no preformed anti-D antibodies be targeted to those predicted to be carrying an Rh D positive fetus, based on NIPT for fetal *RHD*. This applies to both routine and sensitising event immunoprophylaxis, if the result of fetal *RHD* genotyping is available.\* (*Strong recommendation, low certainty of evidence about the size of effect*)  \* See EOP3 and EOP8 |
| **R7** | If fetal Rh D status is not available or is uncertain, the ERG **recommends** that antenatal Rh D immunoprophylaxis be offered to Rh D negative pregnant women with no preformed anti-D antibodies.  (*Strong recommendation, low certainty of evidence about the size of effect*) |
| **Routine antenatal immunoprophylaxis in Rh D negative pregnant women** | |
| **R1** | The ERG **recommends** access to antenatal Rh D immunoglobulin for the prevention of Rh D alloimmunisation in Rh D negative pregnant women with no preformed anti-D antibodies.\* (*Strong recommendation, low to very low certainty of evidence about the size of effect*)  \* See R6 |

| Recommendations and expert opionion points continued | |
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| **Routine dosage regimens in Rh D negative pregnant women** | |
| **R2** | The ERG **recommends** that administration of Rh D immunoglobulin 625 IU at 28 and 34 weeks of pregnancy\* continue in Rh D negative pregnant women with no preformed anti-D antibodies unless NIPT for fetal *RHD*^ has predicted that they are not carrying an Rh D positive fetus. The ERG does not currently suggest changing to a single dose of Rh D immunoglobulin 1500 IU. (*Weak recommendation, low to very low certainty of evidence about the size of effect*)  \* A woman’s pregnancy care schedule and clinical discretion may warrant the administration of  Rh D immunoglobulin within 2 weeks before or after the recommended 28 and 34 weeks of pregnancy. However, if the second dose of Rh D immunoglobulin is given before 34 weeks and the pregnancy goes beyond the due date, the risk of inadequate anti-D coverage at birth increases.  ^ All women should have an ABO/Rh D type and antibody screen performed no later than 10 weeks gestation. Women who are Rh D negative should be retested at 28 weeks unless NIPT for fetal *RHD* has predicted that they are not carrying an Rh D positive fetus. The specimen should be collected before giving prophylactic Rh D immunoglobulin; however, the immunoglobulin can be given before the results are available.[1](#_ENREF_2) |
| **Sensitising event immunoprophylaxis in the first 12 weeks of pregnancy in Rh D negative women** | |
| **R3** | After the following sensitising events in the first 12 weeks of singleton or multiple pregnancy: miscarriage, termination of pregnancy (after 10 weeks gestation), ectopic pregnancy, molar pregnancy and chorionic villus sampling, the ERG **recommends** that a dose of Rh D immunoglobulin 250 IU be given to all Rh D negative women with no preformed anti-D antibodies to prevent Rh D alloimmunisation. (*Strong recommendation, very low certainty of evidence about the size of effect*) |
| **R4** | In the setting of termination of pregnancy before 10 weeks of gestation there is **insufficient evidence to suggest** the routine use of Rh D immunoglobulin.2, 3, 4  *(Discretionary [weak] recommendation, expert consensus)* |
| **EOP4** | For sensitising events in the first 12 weeks of pregnancy where there is any uncertaintly with gestational age, consider Rh D immunoglobulin. Consider ultrasound to confirm gestational age. |
| **R5** | In Rh D negative women with an ongoing pregnancy who have uterine bleeding in the first 12 weeks of pregnancy there is **insufficient evidence to support** the routine use of Rh D immunoglobulin. However, where the bleeding is repeated, heavy or associated with abdominal pain or significant pelvic trauma, immunoprophylaxis may be considered in women with no preformed anti-D antibodies. (*Qualified [weak] recommendation, expert consensus*) |
| **EOP5** | At all times when Rh D immunoglobulin is being administered for a sensitising event, it should be given as soon as practical within 72 hours. If delayed beyond 72 hours, the dose should be given up to 10 days from the sensitising event, but may have lower efficacy. |
| **EOP6** | For repeated sensitising events in the first 12 weeks of pregnancy, there is no evidence to guide practice. Specialist obstetric consultation is advised regarding further administration of Rh D immunoprophylaxis. For new sensitising events a repeated dose of Rh D immunoglobulin may be indicated. For ongoing uterine bleeding alone, a repeat dose of Rh D immunoglobulin (250 IU if during the first 12 weeks and 625 IU if after) may be appropriate after an interval of 6 weeks.5, 6 |
| **Sensitisting event immunoprophylaxis beyond the first 12 weeks of pregnancy in Rh D negative women** | |
| **EOP8** | A dose of Rh D immunoglobulin 625 IU should be offered to every Rh D negative woman with no preformed anti-D antibodies, unless NIPT for fetal *RHD* has predicted the fetus to be Rh D negative, to ensure adequate protection against alloimmunisation for the following indications after 12+6 weeks of pregnancy:   * genetic studies (chorionic villus sampling, amniocentesis and cordocentesis) * abdominal trauma considered sufficient to cause FMH, even if FMH testing is negative * each occasion of revealed or concealed antepartum haemorrhage. Where the woman suffers unexplained uterine pain the possibility of concealed antepartum haemorrhage (and the need for immunoprophylaxis) should be considered * external cephalic version (successful or attempted) * miscarriage or termination of pregnancy. |

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| Recommendations and expert opionion points continued | |
| **Sensitisting event immunoprophylaxis beyond the first 12 weeks of pregnancy in Rh D negative women** | |
| **EOP9** | For sensitising events after 20 weeks of pregnancy, the magnitude of FMH should be assessed, and further doses of Rh D immunoglobulin administered if required.\*  \*The first dose of the Rh D immunoglobulin should be given without waiting for the result of the test for FMH.  See Point 4.3 of the British Committee for Standards in Haematology *Guidelines for the estimation of fetomaternal*  *haemorrhage.*7  See *Dosing of Rh D immunoglobulin following fetomaternal haemorrhage quantitation* |
| **EOP10** | For ongoing uterine bleeding alone beyond 12 weeks gestation a further dose of Rh D immunoglobulin (625 IU) may be appropriate at 6 weekly intervals.[8](#_ENREF_8) New sensitising events should be managed with a further dose of Rh D immunoglobulin (625 IU) and assessment of FMH (after 20 weeks or where otherwise indicated) with additional dosing to cover large volume FMH if required (100 IU for each mL of fetal red cells beyond 6 mL).\*  \*See *Dosing of Rh D immunoglobulin following fetomaternal haemorrhage quantitation*. |
| **EOP11** | In reference to antenatal sensitising events after 20 weeks of pregnancy and after giving birth, a maternal sample to assess the volume of FMH should be taken before administration of Rh D immunoglobulin. At no time should Rh D immunoglobulin be delayed based on, or pending, the results of testing to quantitate FMH. Between 13 and 20 weeks of pregnancy, the magnitude of FMH may be assessed at clinical discretion. |
| **EOP12** | The magnitude of the FMH should be assessed by a method capable of quantifying a haemorrhage of ≥ 6 mL of fetal red cells (equivalent to 12 mL of whole blood). Flow cytometry is accepted as the most accurate quantitative test for FMH and is the method of choice for quantitation if readily available. Where FMH quantitation shows that FMH greater than that covered by the dose already administered has occurred, an additional dose or doses of Rh D immunoglobulin sufficient to provide immunoprophylaxis must be administered as soon as practical within 72 hours.\* If delayed beyond 72 hours, the dose should be given up to 10 days from the sensitising event, but may have lower efficacy.  \* See *Dosing of Rh D immunoglobulin following fetomaternal haemorrhage quantitation*. |
| **EOP13** | For large bleeds ≥ 6 mL of fetal red cells (equivalent to 12 mL of whole blood), follow-up testing should be performed on a sample collected 48 hours post intravenous Rh D immunoglobulin administration or 72 hours post intramuscular Rh D immunoglobulin administration, to determine whether further dosing is required. Supplemental Rh D immunoglobulin should be administered if the test for FMH is still positive.\* If testing for fetal cells is negative on a follow-up sample, no further testing is required.  \* See *Dosing of Rh D immunoglobulin following fetomaternal haemorrhage quantitation*. |
| **Targeted immunoprophylaxis in postnatal Rh D negative women** | |
| **R8** | The ERG currently **recommends** that postnatal Rh D immunoprophylaxis (Rh D immunoglobulin 625 IU) continue to be administered to all Rh D negative women with no preformed anti-D antibodies who have a baby who is predicted to be Rh D positive based on NIPT for fetal *RHD*, or cord blood or neonatal Rh D typing.\* The cord blood or neonatal testing should be performed regardless of the results of NIPT for fetal *RHD*, but need not delay administration of Rh D immunoprophylaxis when the fetus has been shown to be *RHD* positive by NIPT testing. If the baby is Rh D positive, administer Rh D immunoglobulin even if the NIPT predicted an Rh D negative baby. *(Strong recommendation, high certainty of evidence)*  \* If the newborn has a weak or variant Rh D type, consult a haematopathologist in regard to interpretation of results and management. |
| **High body mass index (BMI)** | |
| **R12** | The ERG **does not currently support** an increased dose of Rh D immunoglobulin or changes in laboratory testing on the basis of high BMI in Rh D negative pregnant women. *(Weak recommendation, very low certainty of evidence about the size of effect)* |
| **EOP7** | Rh D immunoglobulin must be given by deep intramuscular injection. For women with a BMI of more than 30, particular consideration should be given to factors that may affect the adequacy of the injection (e.g. the site of administration and the length of the needle used). |

ABO: ABO blood group system; BMI: body mass index; EOP: expert opinion point; ERG: Expert Reference Group; FMH: fetomaternal haemorrhage; IU: international units; NIPT: non-invasive prenatal testing; R: recommendation.

anti-D - refers to circulating antibodies; RHD - refers to genotype; Rh D immunoglobulin - refers to the product; Rh D positive/negative - refers to blood type.

## Summary of guidance on the use and timing of pathology testing

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| **Test** | **Timing** | **Target group** |
| ABO/Rh D type and antibody screen | First visit (no later than 10 weeks) | All pregnant women |
| NIPT for fetal *RHD* | From 11+0 weeks of pregnancy | All Rh D negative pregnant women |
| Magnitude of FMH\* | * After 20 weeks of pregnancy * At delivery | Rh D negative women following birth or a sensitising event during pregnancy (after 20 weeks) |
| Rh D type and antibody screen (Retest) | 28 weeks (prior to administration of Rh D immunoglobulin) | Rh D negative pregnant women (unless NIPT for fetal *RHD* has predicted that they are not carrying an Rh D positive fetus) |
| Cord blood or neonatal testing for Rh D type and direct antiglobulin test | At delivery | All babies of Rh D negative women |
| Follow up testing for large FMH\* | 48 hours post IV Rh D immunoglobulin administration (or 72 hours post IM Rh D immunoglobulin administration) | Rh D negative women following FMH ≥ 6 mL of fetal red cells (equivalent to 12 mL of whole fetal blood) |

FMH: fetomaternal haemorrhage, IM: intramuscular, IV: intravenous, NIPT: non-invasive prenatal testing

*RHD -* refers to genotype, Rh D immunoglobulin - refers to the product, Rh D positive/negative - refers to blood type.

\* The magnitude of FMH should be assessed by a method capable of quantifying a haemorrhage of ≥6 mL of fetal red cells (equivalent to 12 mL of whole blood). Flow cytometry is accepted as the most accurate quantitative test for FMH and is the method of choice for quantitation if readily available (Refer to EOP12).quantitation if readily available (Refer to EOP11).

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## Summary of guidance on the use and timing of Rh D immunoglobulin

| **Clinical indication** | **Rh D immunoglobulin dose and timing** | **Target group** |
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| **Routine immunoprophylaxis** | | |
| Routine antenatal immunoprophylaxis | 625 IU  At 28 and 34 weeks of pregnancy | Rh D negative pregnant women with no preformed anti-D antibodies (unless NIPT for fetal *RHD* has predicted that they are not carrying an Rh D positive fetus) |
| Routine postnatal immunoprophylaxis | 625 IU  After giving birth | All Rh D negative women with no preformed anti-D antibodies after giving birth to an Rh D positive baby (based on cord blood or neonatal Rh D typing\*).  If the baby is Rh D postive, administer Rh D immunoglobulin even if the NIPT predicted an Rh D negative baby.  If the baby is Rh D positive and is born preterm, give the postnatal dose even if the birth is within 72 hours of a dose given for routine antenatal immunoprophylaxis or for a sensitising event.  \* Cord blood or neonatal testing should be performed regardless of NIPT results for fetal *RHD*. |

FMH: fetomaternal haemorrhage, IM: intramuscular, IU: international units, NIPT: non-invasive prenatal testing

anti-D - refers to circulating antibodies, *RHD -* refers to genotype, Rh D immunoglobulin - refers to the product, Rh D positive/negative - refers to blood type.

## Summary of guidance on the use and timing of Rh D immunoglobulin for sensitising event immunoprophylaxis

| Clinical indication | Rh D immunoglobulin | | Target group |
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| Dose | Timing |
| **First 12 weeks of pregnancy:**   * miscarriage * termination of pregnancy (after 10 weeks gestation) * ectopic pregnancy * molar pregnancy * chorionic villus sampling | 250 IU | As soon as practical within 72 hours. If delayed beyond 72 hours, the dose should be given up to 10 days from the sensitising event, but may have lower efficacy | All Rh D negative women with no preformed anti-D antibodies |
| * ongoing uterine bleeding alone | 250 IU | Where bleeding is repeated, or heavy, a repeat dose may be appropriate after an interval of 6 weeks |  |
| **After 12+6 weeks of pregnancy:**   * genetic studies (chorionic villus sampling, amniocentesis and cordocentesis) * abdominal trauma considered sufficient to cause FMH, even if FMH testing is negative * each occasion of revealed or concealed antepartum haemorrhage. Where the woman suffers unexplained uterine pain the possibility of concealed antepartum haemorrhage (and the need for immunoprophylaxis) should be considered * external cephalic version (successful or attempted) * miscarriage or termination of pregnancy | 625 IU | As soon as practical within 72 hours. If delayed beyond 72 hours, the dose should be given up to 10 days from the sensitising event, but may have lower efficacy | All Rh D negative women with no preformed anti-D antibodies (unless NIPT for fetal *RHD* has predicted the fetus to be Rh D negative) |
| * ongoing uterine bleeding alone | 625 IU | Where bleeding is repeated, or heavy, a repeat dose, may be appropriate at 6 weekly intervals |  |
| **Large FMH ≥ 6mL of fetal red cells (equivalent to 12mL of whole blood):**   * antepartum * postpartum | 625 IU as initial dose with follow up dose according to FMH quantitation | As soon as possible.  Follow laboratory or specialist obstetric advice for additional doses of IM Rh D immunoglobulin or IV Rh D immunoglobulin, and for follow-up testing | All Rh D negative women with no preformed anti-D antibodies (unless NIPT for fetal *RHD* has predicted the fetus to be Rh D negative) |

FMH: fetomaternal haemorrhage, IM: intramuscular, IU: international units; IV: intravenous, NIPT: non-invasive prenatal testing

anti-D - refers to circulating antibodies, *RHD -* refers to genotype, Rh D immunoglobulin - refers to the product, Rh D positive/negative - refers to blood type

## Dosing of Rh D immunoglobulin after fetomaternal haemorrahge quantitation

For Rh D negative pregnant women, a maternal blood sample should be collected for quantitation of FMH following sensitising events after 20 weeks of pregnancy and after giving birth; the routine dose of Rh D immunoglobulin of 625 IU should be administered. This dose is sufficient to cover FMH of up to 6 mL Rh D positive fetal red cells (equivalent to about 12 mL of fetal whole blood), which will account for 99% of FMH.

For FMH volumes greater than 6 mL fetal red cells, an additional dose of Rh D immunoglobulin is required, and should be calculated at 100 IU per mL of fetal red cells in excess of 6 mL covered by the standard initial 625 IU dose. The required dose should be rounded up to the nearest full vial or vials.

Doses that require intramuscular injection of a volume of Rh D immunoglobulin of more than 5 mL should be divided and administered in separate intramuscular injections. Intravenous Rh D immunoglobulin may be used for the management of large FMH where administration of intramuscular Rh D immunoglobulin is either contraindicated or not practical.

For very large FMH volumes that would require more than two intramuscular injections, use of the intravenous product Rhophylac 1500 IU is recommended, at a dose of 100 IU/1 mL fetal red cells in excess of the 6 mL that is covered by the standard initial 625 IU dose.

After the initial 625 IU standard dose for sensitising events and following birth, the following table guides the additional Rh D immunoglobulin dosing for large FMH ≥6mL.

**Dosing of Rh D immunoglobulin after fetomaternal haemorrhage quantitation**

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| FMH volume (fetal red cells) | Total dose of Rh D immunoglobulin required | Initial dose of IM  Rh D immunoglobulin  (625 IU) for sensitising event or birth | Additional vials of  Rh D immunoglobulin (625 IU) for IM injection | Additional vials of Rhophylac (1500 IU) for IV injection |
| < 6 mL | 600 IU | 1 | 0 | - |
| ≥ 6 to < 12 mL | 1200 IU | 1 | 1 | - |
| ≥ 12 to < 18 mL | 1800 IU | 1 | 2\* | - |
| 1 | - | 1\* |
| ≥ 18 to < 21 mL | 2100 IU | 1 | - | 1 |
| ≥ 21 to < 36 mL | 3600 IU | 1 | - | 2 |
| ≥ 36 mL | FMH volume in mL fetal red cells multiplied by 100 IU | 1 | - | Total dose of Rh D immunoglobulin required  (less 600 IU if already given initial dose) divided by 1500 IU (round up to a full vial) |

FMH: fetomaternal haemorrhage; IM: intramuscular; IU: international units; IV: intravenous

\*2 vials of 625 IU can be administered as a single injection or as separate injections, however to avoid discomfort associated with a larger volume IM injection or 2 additional injections, it may be more practical to offer IV Rhophylac 1500 IU instead.





**References**

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