This information was up to date at the time of release to the Heads of Midwifery.
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Updating arrangements for the formulary should be decided upon and implemented at a local level.

Anti D Immunoglobulin 1500 units D Gam® and Rhophylac ® Postnatal

Legal status (GSL, P or POM on exemption list, or PGD)	▪ POM - midwife may administer as medicine is on midwives exemptions list
Patient group	Postnatal Rhesus-negative women who have given birth to a Rhesus positive baby.
Clinical indication	Prevent sensitisation and subsequent destruction of baby's blood cells if Rhesus positive in subsequent pregnancies.
Pharmacology (Onset and duration of action where appropriate)	Anti-D immunoglobulin contains specific antibodies against the RhD antigen and it is given to prevent the mother producing antibodies which can destroy the fetus's blood cells if RhD- positive in current and subsequent pregnancies. Antibodies are measurable 4 to 8 hours after administration and a peak is obtained after 2 to 5 days. The half life of circulation is 2 to 5 weeks in women with normal levels of IgG.
Pharmaceutical form, strength, route of administration	Solution of Human Anti-D Immunoglobulin Ph.Eur D-GAM®: 1500 international units per vial. Or Rhophylac®: 1500 international units in 2ml prefilled syringe. For intramuscular injection preferably into the deltoid muscle. In patients with a body mass index (BMI) ≥30 intravenous administration should be considered (Rhophylac® brand).
Dose, frequency and maximum number of doses or period of time for administration or supply	1500 international units (iu) by IM injection within 72 hours of delivery but check results of Kleihauer acid elution test (see below). The standard dose of 1500iu of Human Anti-D Immunoglobulin will suppress immunisation by up to 12ml of fetal red cells. In cases of bleeds in excess of 12ml, additional Anti-D immunoglobulin should be administered depending on the volume of transplacental haemorrhage determined by a Kleihauer acid elution screening test. BTS will advise on dosage. Maximum of one dose or as advised by BTS.
Contra-indications/exclusion criteria	▪ known RhD-positive individuals including those who are Du positive ▪ RhD-negative individuals known to have immune Anti-D antibodies ▪ known hypersensitivity to any of the components ▪ consent not given • patients with severe thrombocytopenia or other disorders of haemostasis

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Cautions and action that will be taken if a caution applies	▪ if large dose of more than 5ml has to be given then it is advisable to administer it in divided doses at different sites ▪ haemorrhagic disorders- refer to doctors who may administer D-GAM® subcutaneously or Rhophylac® by intravenous injection ▪ check for and document any allergies ▪ check and document past medical and drug history and current medication to ascertain potential for overdose ▪ if a caution applies consult with a doctor ▪ document consultation in maternity record
Medicine interactions and action that will be taken if a patient is taking a medicine that may interact	▪ it must not be mixed with vaccines or other medicinal products ▪ it may impair effectiveness of live virus vaccines if given within 3 months of Anti-D ▪ after injection of immunoglobulin, the transitory rise of the various passively transferred antibodies in the patient's blood may result in misleading positive results in serological testing – including the Coombs or antiglobulin test ▪ if MMR vaccine (measles, mumps and rubella) is given within 3 months of Anti-D for rubella protection serological testing should be performed 6 – 8 weeks after vaccination to assess the need for re-immunisation ▪ if there is a clinically significant drug interaction, consult with a doctor before administration or supply ▪ document consultation in maternity record ▪ refer to current BNF for latest information on interactions
Potential adverse reactions and side effects including actions to be taken if adverse drug reaction is suspected	▪ *intramuscular injections may lead to some short-term discomfort at the site of administration, which can be prevented by dividing larger doses over several injection sites* ▪ *occasionally malaise, chills, pyrexia, cutanous reactions and headache - rarely nausea, vomiting, hypotension, tachycardia and allergic reactions* ▪ *on very rare occasions, anaphylactoid reactions may occur and it can be associated with bradycardia chest pain, dyspnoea, palpitations, collapse or shock particularly in certain categories of patients with selective IgA deficiency* ▪ *as with all product derived from blood the transmission of infectious agents cannot be totally excluded* ▪ *on labour* *N/A* ▪ *on the neonate* *Nil* ▪ *on breast feeding* *N/A* ▪ *if a serious adverse reaction is suspected please report to the MHRA Yellow Card Scheme http://yellowcard.mhra.gov.uk/*

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Overdose	▪ no data are available on overdose but it is not likely to produce more frequent or severe adverse reaction than normal dose ▪ if a RhD negative woman, however, has been given RhD positive blood or other products containing RhD positive red blood cells and receive anti-D immunoglobulin she should be monitored clinically and by biological parameters, because of the risk of haemolytic reaction ▪ immediate assessment/treatment is essential - refer to medical staff ▪ manage in accordance with established treatment guidelines or see BNF overdose section ▪ for further advice contact National Poisons Centre 0344 892 0111
Action if patient declines	▪ refer to authorised prescriber or doctor ▪ document in maternity record
Additional advice and information	▪ supply the manufacturer's patient information leaflet if requested
Patient monitoring arrangements during and after treatment and follow-up required	Women should remain with the midwife until the midwife is satisfied that she is well following the administration of anti-D immunoglobulin (for at least 20 minutes). Adrenaline 1 in 1000 should be available. If a woman suffers an anaphylactic reaction: • if in hospital call the cardiac arrest team • if outwith the hospital call 999 for an ambulance • administer adrenaline 1 in 1000 as described in the monograph • maintain airway, and • commence basic life support (cardio-pulmonary resuscitation) if there is no pulse Complete documentation in accordance with local guideline. Record product and batch number administered.
Particular storage requirements	▪ The product must be used immediately after opening. ▪ Do not use if solution is cloudy or has deposits. ▪ Store in refrigerator 2-8^{0}C and bring to room temperature before administration. ▪ Do not freeze. ▪ D-GAM® may be stored at ambient temperatures (below 25^{0}C) for one week.

References

1. Summary of Product Characteristics http://www.medicines.org.uk for D-GAM (revised 10.12.2018) and Rhophylac (revised 31.7.2019) accessed 27.12.2019
2. http://www.bnf.org