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.

AntiD Immunoglobulin-human 1500 units D-Gam ® and Rhophylac® Routine antenatal

Legal status (GSL, P or POM on exemption list, or PGD)	▪ POM - midwife may administer as medicine is on midwives exemptions list
Patient group	Rhesus (RhD) - negative women who have been given the information leaflet and have had an opportunity to discuss it with a midwife, obstetrician or GP and wish to go ahead with the prophylaxis at ideally 28 weeks gestation.
Clinical indication	Routine antenatal prophylaxis at 28 weeks gestation.
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.
Dose, frequency and maximum number of doses or period of time for administration or supply	A single dose given as below. 1500 international units at 28-30 weeks by IM injection after a blood sample has been obtained to be sent to BTS for antibody testing. Women who present late and have missed the 28-30 weeks gestation window should be referred in accordance with local guidelines if they wish to receive prophylaxis. Woman who had anti-D immunoglobulin for a sensitising event should receive prophylaxis at the above time irrespective of time of administration for prophylaxis. The injection should be given at the start of the appointment so that the midwife can observe the woman for at least 20 minutes following administration of anti-D immunoglobulin.

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Contra-indications/exclusion criteria	▪ known hypersensitivity to any component of the medicine ▪ known RhD- positive individuals including those who are Du positive ▪ RhD- negative individuals known to have immune Anti-D antibodies ▪ consent not given ▪ women of less than 28 weeks gestation
Cautions and action that will be taken if a caution applies	▪ 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 medicine interaction, consult with a doctor before administration or supply ▪ document consultation in maternity record ▪ refer to current BNF for latest information on interactions

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Potential adverse reactions and side effects including actions to be taken if adverse medicine reaction is suspected	▪ *intramuscular injections may lead to some short-term discomfort at the site of administration* ▪ *occasionally malaise, chills, fever, cutaneous reaction 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/
Overdose	▪ no data are available on overdose but it is not likely to produce more frequent or severe adverse reaction than normal dose - however, if a RhD negative woman has been given RhD positive blood or other products containing RhD positive red blood cells and receives 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	▪ women should be given an information leaflet for women with rhesus negative blood group and antenatal Anti-D injections ▪ the signs and symptoms of allergic reactions should be explained ▪ alert the woman to the potential of further doses if they have a post-sensitizing event ▪ advise to contact midwife/GP if condition worsens or symptoms persist ▪ supply the manufacturer's patient information leaflet if requested

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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 call the cardiac arrest team if in hospital if outwith the hospital call 999 for an ambulance administer adrenaline 1 in 1000 as described in the monograph maintain airway commence basic life support (cardio-pulmonary resuscitation) if there is no pulse Complete local documentation in accordance with local guideline. Record product and batch number administered.
Particular storage requirements	Store in refrigerator 2-8 C and bring to room temperature before administration. The product must be used immediately after opening. Do not use if solution is cloudy or has deposits. Do not freeze. D-GAM® may be stored at ambient temperatures (below 25 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