health
Department:
Health
REPUBLIC OF SOUTH AFRICA

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NOTICE: RECOMMENDATIONS FOR RESTRICTED USE OF ANTI-D IMMUNOGLOBULIN.

The Primary Health Care (PHC), and Paediatric and Adult Hospital Level Standard Treatment Guidelines (STGs) and Essential Medicines List (EML) currently recommends the use of Anti-D immunoglobulin for various indications. The supplier of Anti-D immunoglobulin, however, is unable to meet the contractual obligation due to unforeseen operational delays. The supplier anticipates that the supply of Anti-D immunoglobulin will resume on 27 July 2026.

There are no available therapeutic alternative agents for Anti-D immunoglobulin. Due to the current supply problems, restricted use of Anti-D immunoglobulin is recommended until supply stabilises.

The following recommendations guide the restricted use of Anti-D immunoglobulin for indications listed in the latest Adult and Paediatric Hospital Level STGs and EML, and the PHC STGs and EML:

Indications in the Adult Hospital Level, 2026	Current recommendation in STGs and EML	Recommendation for restricted use
5.8.3 Mid-trimester miscarriage (from 13–22 weeks gestation)	If Rh-negative: (O36.0) • Anti-D immunoglobulin, IM, 100 mcg as a single dose.	Not applicable *(No alternative)*
5.9.2 TOP: from the thirteenth week (12 weeks and 1 day) up to the twentieth week (20 weeks and 0 days)	If Rh-negative: O36.0 • Anti-D immunoglobulin, IM, 100 mcg as a single dose.	Not applicable *(No alternative)*
6.18 The Rhesus negative woman	**GENERAL MEASURES** **Maternal serum antibodies absent** **Prevention** Test for maternal serum antibodies at 'booking', 28- and 34-weeks' gestation. During pregnancy, give prophylactic anti-D immunoglobulin to the mother within 72 hours of a potentially sensitising event. **MEDICINE TREATMENT** After a termination of pregnancy (TOP), miscarriage, ectopic pregnancy or amniocentesis 13-22 weeks: • Anti-D immunoglobulin, IM, 50 mcg. After external cephalic version or potentially sensitizing event ≥22 weeks: • Anti-D immunoglobulin, IM, 100 mcg.	Carefully consider antenatal interventions that may cause trans-placental bleeding in the unsensitised Rh negative woman (e.g. amniocentesis, external cephalic version, cordocentesis or chorionic villus sampling). If the biological father is available conduct a rapid Rh test on him; if Rh negative, no further testing or prophylaxis is needed. If the paternal status is unknown test for maternal serum antibodies at 'booking', 28- and 34-weeks' gestation. Cord blood Rh positive, Coomb's positive: • Do not administer anti-D immunoglobulin-maternal antibodies have already crossed the placenta.

	At birth, determine the Rh status of the cord blood and request a Coomb's test: Cord blood Rh negative - no treatment. Cord blood Rh positive, Coomb's negative: • Anti-D immunoglobulin, IM, 100 mcg. If a large feto-maternal haemorrhage is suspected: • Anti-D immunoglobulin, IM, 300 mcg for every 30 mL haemorrhage. o Maximum dose: 1 200 mcg.	• This baby is at risk for haemolytic disease of the newborn/ neonatal jaundice - refer to a specialist. If a large feto-maternal haemorrhage is suspected: Do a maternal blood Kleihauer test **(consult a specialist).** **Maternal serum antibodies present.** Consult a specialist (any titre).

Indications in the Paeditric Hospital Level STGs (2026)	Current recommendation in STGs and EML	Recommendation for restricted use
19.2.1.1 Hyperbilirubinaemia, Unconjugated	Mothers of babies with Rh incompatibility should receive: • Anti-D immunoglobulin, IM, 100 mcg as soon as possible after birth but within 72 ours of birth.	Not applicable *(No alternative)*

Indications in the Primary Healthcare Level STGs (2026)	Current recommendation in STGs and EML	Recommendation for restricted use
6.2 Miscarriage	For Rh-negative non-sensitised women from 13 to 22 weeks Anti-D immunoglobulin, IM, 50 mcg preferably within 72 hours but may be given up to 7 days following management of miscarriage.	• Restrict the use of Anti-D immunoglobulin to miscarriages in the 2nd trimesters[1]. The use of Anti-D immunoglobulin in the first trimester is not recommended in the EML.
6.5 Intrapartum care	Rh-negative mother O36.0 Check baby's Rh status: do not give anti-D if the baby is Rh-negative, or if the mother has Anti-Rh antibodies. Administer to Rh-negative mother, if baby is Rh-positive or baby's Rh group is unknown: • Anti-D immunoglobulin, IM, 100 mcg, preferably within 72 hours but can be given up to 7 days after delivery.	Obtain a fetal Rh status at birth in all cases – using onsite Rh test kit. If the baby is Rh-positive: • Administer Anti-D immunoglobulin, IM, 100 mcg, to Rh-negative mother, preferably within 72 hours but can be given up to 7 days after delivery. If the baby is Rh negative: • Do not administer Anti-D immunoglobulin, to the Rh-negative mother.

For other indications not listed in the STGs and EML:

- In women who are Rh negative, after delivery of the baby, clamp the cord on the fetal side only. Let the placental side bleed freely. Avoid manual removal of the placenta if at all possible. [2]
- Do not administer routine antenatal Anti-D immunoglobulin prophylaxis at 28 and 34 weeks to unsensitised Rh negative women. [3]
- A woman with "weak D" (also known as Du-positive) should not receive Anti-D immunoglobulin. [4]
- Consider omitting Anti-D immunoglobulin to unsensitised Rh negative women who undergo postpartum tubal ligation. [5]
- Sensitised, non-pregnant woman should be encouraged to donate blood.

[1] The risk of transmission is greater the more advanced the pregnancy. There is insufficient data available to evaluate the practice of routine administration of anti-D in an unsensitised Rh negative mother after spontaneous miscarriage.
Karanth L, Jaafar SH, Kanagasabai S, et al. Anti-D administration after spontaneous miscarriage for preventing Rhesus alloimmunisation. Cochrane Database Syst Rev. 2013 Mar 28;(3):CD009617. https://www.ncbi.nlm.nih.gov/pubmed/2354358
[2] This may minimise the risk of trans-placental bleeding. *Cronje HS, Cilliers JBF, Pretorius MS. Clinical Obstetrics: A South African Perspective. Van Schaik Publishers; 2010. p 810.*
[3] There is no difference in risk of immunisation when routine administration of Anti-D immunoglobulin at 28 and 34 weeks, compared to placebo.
McBain RD, Crowther CA, Middleton P. Anti-D administration in pregnancy for preventing Rhesus alloimmunisation. Cochrane Database Syst Rev. 2015 Sep 3;(9):CD000020. https://www.ncbi.nlm.nih.gov/pubmed/26334436
[4] Fung Kee Fung K, Eason E, et al; Maternal-Fetal Medicine Committee, Genetics Committee. Prevention of Rh alloimmunization. J Obstet Gynaecol Can. 2003 Sep;25(9):765-73. https://www.ncbi.nlm.nih.gov/pubmed/12970812
[5] Ensure that the family is indeed complete, and no more children is expected. Anti-D antibodies will only be a risk in a subsequent pregnancy. Women who do not receive Anti-D immunoglobulin after sterilization/ tubal ligation should be advised that they need to check for antibodies prior to any investigations for sterilization reversal in future.

Note: It is important to inform women suspected of sensitisation and who were not administered Anti-D immunoglobulin prophylaxis of the current supply constraints. These women require a follow-up examination that includes testing for antibodies 3 months' post-delivery, as well as prior to any future pregnancy.

The National Department of Health will provide updated communication as soon as the supply of Anti-D immunoglobulin is confirmed National Bioproducts Institute NPC.

Procurement information

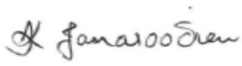
NSN	Product	Supplier	Contract
189755220	Immunoglobulin, Anti-D; 100mcg; injection; 2 ml	National Bioproducts Institute NPC	HP10-2025BIO

Circular implementation and dissemination

Provinces and facilities are reminded to ensure equitable and timely access as per the adult hospital, paediatric hospital and primary health care STGs and EML, above, and to facilitate availability.

Provinces and healthcare facilities are requested to distribute and communicate this information in consultation with the Pharmaceutical and Therapeutics Committees and all other relevant stakeholders.

Kind regards



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