Irish Blood Transfusion Service
Seirbhís Fuilaistriúcháin na hÉireann

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Review

Review: IBTS PMF REVIEW

Level	Owner Role	Actor	Sign-off By
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Change Orders

Changes as described on Change Order:	Change Order No.

Change Orders - Incorporated

Changes as described on Change Order:	Change Order No.
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IRISH BLOOD TRANSFUSION SERVICE

PRODUCT MASTER FILE

TITLE: RED CELLS, SUITABLE FOR NEONATAL USE FOR 5 DAYS AFTER DATE DRAWN

Change Description:
Update to Indications for Use section to provide information pertaining to the use of this component beyond 5 days.

Reason for Change:
To provide clarity regarding the clinical use of the blood component and provide information in relation to the requirement for stock holding of unit(s) < 5 days from date drawn, at all times.

Referenced Documents
N/A

SmartSolve Roles
N/A

Training Type
N/A

SmartSolve Document Category

Category	Mobile	Cryobiology	Website	GDP
Yes / No	No	No	Yes	No

IRISH BLOOD TRANSFUSION SERVICE

PRODUCT MASTER FILE

Title: Red Cells, Suitable for Neonatal Use for 5 Days after Date Drawn

Name of Products: RED CELLS, Suitable for Neonatal Use for 5 Days after Date Drawn /

RED CELLS, Suitable for Neonatal Use for 5 Days after Date Drawn, Irradiated

E Progesa Codabar Component Codes: 54481 / 74421

E Progesa ISBT – 128 Component Codes : C7429V00 / C7442V00.

General Description: A red cell suspension obtained from whole blood by centrifugation, removal of plasma with subsequent addition of a nutrient solution SAG-M. The removal of the majority of leucocytes is achieved by filtration. The selected donors meet the additional criteria for neonatal use.

General Specification:

Parameter	Quality Requirements	Frequency of Control
Volume	231 – 355 ml	100%
Haematocrit	0.50 - 0.70 L/L	1%
Haemoglobin	≥ 40 g/unit	1%
Leucocyte Content	< 1 x 10^6/unit	1%
Haemolysis at end of shelf life	< 0.8% of red cell mass	4 per month (RED CELLS, 04333/E7429V00)
ABO Agglutinins	No HighTitre Anti-A or Anti-B	100%
CMV	CMV ab negative	100%

Labelling: See Appendix I

Storage: Red Cells, Suitable for Neonatal Use for 5 Days after Date Drawn (including Irradiated) should be stored at $4^{o}C \pm 2^{o}C$.

Irradiation: Red Cells, Suitable for Neonatal Use for 5 Days after Date Drawn may be irradiated up to 14 days from date of collection. Post irradiation the storage is 14 days.
If irradiated, product code will change into codabar:74421and ISBT-128 barcode: C7442V00.

Transportation: The air temperature of transport containers for units of Red Cells, Suitable for Neonatal Use for 5 Days after Date Drawn (including Irradiated) should be maintained between $2^{o}C$ and $10^{o}C$ during transport from the Irish Blood Transfusion Service to the place where they are intended for use. Transport time under these conditions normally should not exceed 8 hours.

Indications for Use: Red Cells, Suitable for Neonatal Use for 5 Days after Date Drawn (including Irradiated) are used for augmenting the oxygen carrying capacity of the blood where this is critically reduced in infants requiring large volume transfusion, particularly in the surgical setting, within 5 days from date drawn.

Red Cells, Suitable for Neonatal Use for 5 days after the Date Drawn can be used *beyond* 5 days after the Date Drawn for indications including:

Neonatal resuscitations where:

- The total volume given is not likely to meet or exceed the threshold for Large Volume Transfusion as defined by the local centre. Where the Local Centre does not have a defined threshold for LVT, a threshold of 25 mls/kg should be used.
- The product is within 8 days from the date drawn.
- Where multiple transfusions are given with a product beyond 5 days from the date drawn *and* the total volume received exceeds the threshold for Large Volume Transfusion as defined by the local centre, additional monitoring for transfusion associated hyperkalaemia is available and recommended.
- Where this product is used for large volume transfusion at days 6,7 and 8 this should be reported to the NHO via your haemovigilance team. Reporting is not necessary if used within 5 days from the date drawn.

Routine, semi-urgent or emergency transfusion to neonatal patients where:

- the patient might otherwise receive products covered by IBTS/PMF/SPEC/0209 “Red Cells Suitable for Neonatal Use, Split 1/2/3/4/5”
- The product is within 8 days from the date drawn.

Should this blood component not be used for neonatal transfusion, it may be used for adult use, as per IBTS/PMF/SPEC/0205 ‘’Red Cells’’.

Precautions in Use:

- Compatibility of this component with the intended recipient must be verified by appropriate pre transfusion testing.
- Red Cells, Suitable for Neonatal Use for 5 Days after Date Drawn (including Irradiated) should be transfused through a standard 170 – 200 µm filter.
- No solution should be added to the bag or to the giving set.
- Components should be inspected visually for defects, leakage, abnormal colour or visible clots.
- Red Cells, Suitable for Neonatal Use for 5 Days after Date Drawn (including Irradiated) are not recommended in:
  - large volume transfusion in neonates **unless** the red cells are less than 5 days old.
  - exchange transfusions in newborns.
  - Intrauterine Transfusions
- This component does not contain platelets or soluble coagulation factors.

Adverse Effects Include:

- Circulatory Overload.
- Haemolytic transfusion reaction;
- Non-haemolytic transfusion reaction (mainly chills, fever and urticaria)

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- Pathogen transmission
  - Despite careful donor selection and laboratory screening procedures, infections including Syphilis, Viral Hepatitis, HIV, HTLV 1 & 11 and other viruses and protozoa (e.g. malaria) may, in rare instances, occur.
  - vCJD transmission
  - Transmission of other pathogens that are not tested for or recognised.
  - The risk of CMV transmission is minimal as the components are leucodepleted
  - Sepsis due to bacterial contamination (reduced but not eliminated by bacterial screening)

- Immunological effects
  - Alloimunisation to HLA, HPA and red cell antigens
  - Post Transfusion purpura (PTP), especially in parous female recipients
  - Graft versus host disease due to transfusion of viable lymphocytes can occur, but is minimised by exposure of the suspension to ionising radiation before transfusion
  - Transfusion related Acute Lung injury (TRALI) by donor HLA/granulocyte antibodies

- Metabolic upset
  - Citrate toxicity, especially in neonates and in patients with impaired hepatic function.
  - ↑ K^+ in massive transfusions, especially where patient is hypothermic or acidotic or has impaired renal function.
  - Hypocalcaemia.
  - Hypoglycaemia.
  - Hypokalaemia.
  - We recommend that neonates receiving large volume transfusion are monitored in a suitable clinical environment. Further guidance on suitable monitoring regimens can be obtained through the medical team at IBTS.
  - Where neonatal red cells are used beyond 5 days from the date drawn for large volume transfusion, the risk of hyperkalaemia is higher and we recommend close monitoring. Advise on this can be obtained from the medical team at IBTS if required. If this occurs, the transfusion event should be reported to the National Haemovigilance Office for audit purposes.

- Iron overload
  - In patients on chronic red cell transfusion support programmes.

Serious Adverse Reaction

Please inform the IBTS immediately about any event relating to suspected bacterial sepsis/ transfusion associated bacterial sepsis

Serious adverse reactions should be reported to:

National Haemovigilance Office
Irish Blood Transfusion Service
National Blood Centre
James's Street
Dublin 8

AND

Quality Assurance Manager
Irish Blood Transfusion Service

AT EITHER
National Blood Centre
James's Street
Dublin 8
OR
Munster Regional Transfusion Centre
St Finbarr's Hospital
Douglas Road, Cork

APPENDIX 1

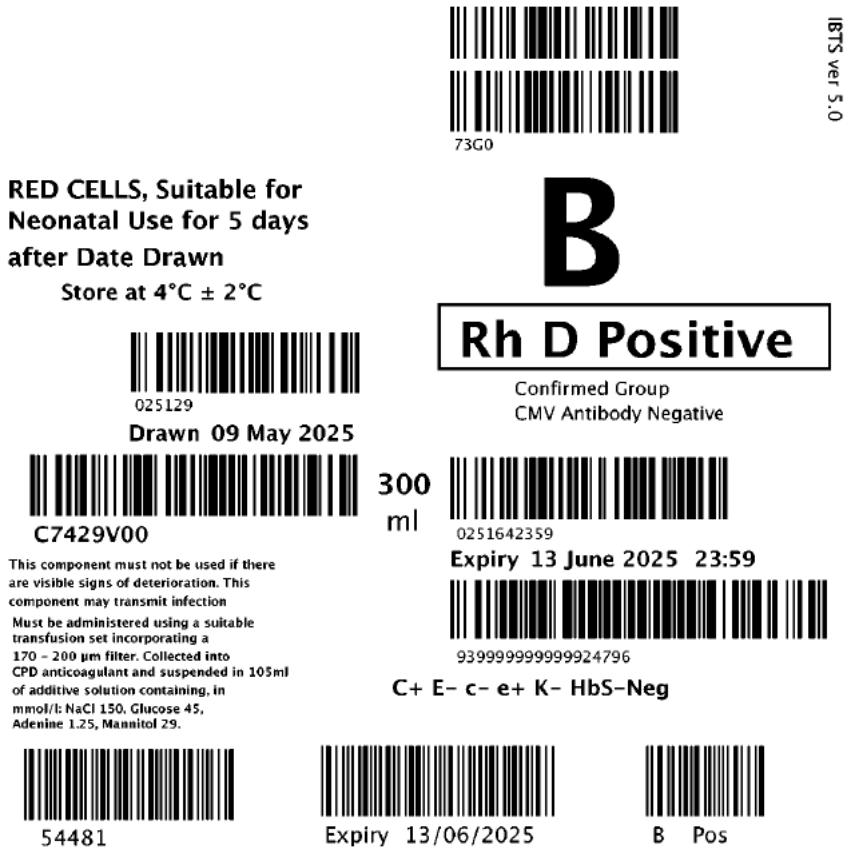
E Progesa Codabar Component Code: 54481

E Progesa ISBT – 128 Component Code: C7429V00

Product Name
RED CELLS, Suitable for Neonatal Use for 5 Days after Date Drawn

Shelf life
35 days

Labelling and Barcode:
(for illustration purposes only – barcodes not suitable for scanning – label not to scale)



APPENDIX II

E Progesa Codabar Component Code: 74421

E Progesa ISBT – 128 Component Code : C7442V00

Product Name
RED CELLS, Suitable for Neonatal Use for 5 Days after Date Drawn, Irradiated

Shelf life
14 days

Labelling and Barcode:
(for illustration purposes only – barcodes not suitable for scanning – label not to scale)