



Irish Blood Transfusion Service

Seirbhís Fuilaeistriúcháin na hÉireann

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Title: **RED CELLS, SUITABLE FOR NEONATAL USE FOR 5 DAYS
AFTER DATE DRAWN**
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Review

Review: IBTS PMF REVIEW

<u>Level</u>	<u>Owner Role</u>	<u>Actor</u>	<u>Sign-off By</u>
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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.**
IBTS/CO/0219/25

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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:

Revise the Labelling and Barcode Illustrations.

Reason for Change:

To update the PMFs with new Label Versions (Ref CC 208/23 & 002/24)

Change order No.:

IBTS/CO/0219/25

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

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Storage:	Red Cells, Suitable for Neonatal Use for 5 Days after Date Drawn (including Irradiated) should be stored at 4°C ± 2°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°C and 10°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.
Precautions in Use:	<ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> - 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)
- 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
 - Alloimmunisation 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.
- 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

Verify when in Use. Status CURRENT Effective 19 May 2025

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)



IBTS ver 5.0

RED CELLS, Suitable for
Neonatal Use for 5 days
after Date Drawn

Store at 4°C ± 2°C



025129

Drawn 09 May 2025



C7429V00

This component must not be used if there are visible signs of deterioration. This component may transmit infection. Must be administered using a suitable transfusion set incorporating a 170 – 200 µm filter. Collected into CPD anticoagulant and suspended in 105ml of additive solution containing, in mmol/l: NaCl 150, Glucose 45, Adenine 1.25, Mannitol 29.



54481



Expiry 13/06/2025



B Pos

B

Rh D Positive

Confirmed Group
CMV Antibody Negative



0251642359

Expiry 13 June 2025 23:59



93999999999924796

C+ E- c- e+ K- HbS-Neg

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)



IBTS ver 5.0

RED CELLS, Suitable for
Neonatal Use for 5 days
after Date Drawn, Irradiated
Store at 4°C ± 2°C

B

Rh D Negative

CMV Antibody Negative
IRRADIATED
Confirmed Group



025129

Drawn 09 May 2025



C7442V00

This component must not be used if there are visible signs of deterioration. This component may transmit infection. Must be administered using a suitable transfusion set incorporating a 170 – 200 µm filter. Collected into CPD anticoagulant and suspended in 105ml of additive solution containing, in mmol/l: NaCl 150, Glucose 45, Adenine 1.25, Mannitol 29.

300
ml



0251642359

Expiry 13 June 2025 23:59



93999939999917796

C- E- c+ e+ K- Lua- HbS-Neg



74421



Expiry 13/06/2025



B Neg