



Irish Blood Transfusion Service

Seirbhís Fuilaidriúcháin na hÉireann

Document Detail

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Title: **WHOLE BLOOD, 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>
1	DOCUMENT CONTROLLER	BECKY WHITE	BECKY WHITE
2	SSCD WRITER IBTS	LIAM MORGAN	LIAM MORGAN
3	COMPONENTS HEAD OF DEPT MRTC	AINE FITZPATRICK	AINE FITZPATRICK
3	LABS PHS DIR IBTS	BARRY DOYLE	BARRY DOYLE
3	MEDICAL & SCIENTIFIC DIRECTOR	ANDREW GODFREY	ANDREW GODFREY
3	SSCD HEAD OF DEPT IBTS	AILEEN FARRELLY	AILEEN FARRELLY
4	QUALITY ASSURANCE REVIEWER IBTS	COLIN JOHNS	COLIN JOHNS

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: WHOLE BLOOD, 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: Whole Blood, Suitable for Neonatal Use for 5 Days after Date Drawn

Name of Products:

- WHOLE BLOOD, Suitable for Neonatal Use for 5 days after Date Drawn. HCT Range: 0.50 - 0.60
- WHOLE BLOOD, Suitable for Neonatal Use, Irradiated HCT Range: 0.50 - 0.60

And

- WHOLE BLOOD, Suitable for Neonatal Use for 5 days after Date Drawn. HCT Range: 0.50 - 0.55
- WHOLE BLOOD, Suitable for Neonatal Use, Irradiated HCT Range: 0.50 - 0.55

E Progesa Codabar Component Codes:

54350 / 39360 and 39361 / 39362

E Progesa ISBT -128 Component Codes:

E8215V00 / E8212V00 and E8217V00 / E8216V00

General Description: Plasma reduced whole blood obtained from:
WHOLE BLOOD, Suitable for Neonatal Use for 5 days after Date Drawn
or

WHOLE BLOOD, Reconstituted, Suitable for Neonatal Use obtained
by centrifugation and removal of part of the plasma or additive solution,
respectively.

General Specification:

Parameter	Quality Requirement	Frequency of Control
Volume	volume monitored by SPC	100%
Haematocrit	0.50 - 0.60 L/L 0.50 – 0.55 L/L	100 %
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 annum (including irradiated)
ABO Agglutinins	No HighTitre Anti-A or Anti-B	100%
CMV	CMV ab negative	100%

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Labelling: See Appendix I and II

Storage: Whole Blood, Suitable for Neonatal Use for 5 days after date drawn / Whole Blood, Suitable for Neonatal Use, Irradiated (with Hct. ranges of 0.50-0.60 L/L or 0.50-0.55 L/L,) should be stored at $4^{\circ}\text{C} \pm 2^{\circ}\text{C}$.
For exchange or massive transfusion of neonates it should be used within 5 days after date drawn and up to 24 hrs after irradiation. For adult use it can be stored up to 28 days.

Irradiation: Whole Blood, Suitable for Neonatal Use for 5 days after date drawn for exchange should be irradiated before transfusion provided this does not unduly delay the transfusion. Post irradiation the product should be used within 24 hours. It **must** be irradiated prior to transfusion where the neonate has had a previous intrauterine transfusion. If irradiated, the component codes will change to 39360/E8212V00 and 39362/E8216V00.

Transportation: The air temperature of transport containers for units of Whole Blood, Suitable for Neonatal Use for 5 days after date drawn / Whole Blood, Suitable for Neonatal Use, Irradiated (with Hct. ranges of 0.50-0.60 L/L or 0.50-0.55 L/L,) 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: Whole Blood, Suitable for Neonatal Use for 5 days after date drawn / Whole Blood, Suitable for Neonatal Use, Irradiated (with Hct. ranges of 0.50-0.60 L/L or 0.50-0.55 L/L,) are used to augment the oxygen delivery capacity of the blood where this is critically impaired. Typically indicated for:

- Exchange transfusion of neonates.
- Massive transfusion in neonates and small infants.
- adult transfusion.

Precautions in Use:

- Compatibility of this component with the intended recipient must be verified by suitable pre transfusion testing.
- Whole Blood, Suitable for Neonatal Use for 5 days after date drawn / Whole Blood, Suitable for Neonatal Use, Irradiated (with Hct. ranges of 0.50-0.60 L/L or 0.50-0.55 L/L,) 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.
- Whole Blood, Suitable for Neonatal Use for 5 days after date drawn / Whole Blood, Suitable for Neonatal Use, Irradiated (with Hct. ranges of 0.50-0.60 L/L or 0.50-0.55 L/L,) are not recommended in:
 - various types of plasma intolerance.
 - repeated leucocyte antigen/antibody mediated reaction unresponsive to medication

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Adverse Effects Include:

- Circulatory Overload.
- Haemolytic transfusion reaction;
- Non-haemolytic transfusion reaction (mainly chills, fever and urticaria).
The risk is reduced by leucodepletion and washing
- 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)
- Metabolic upset
 - Possible elevated potassium level in massive transfusions, especially where patient is hypothermic or acidotic or has impaired renal function.
 - Citrate toxicity, especially in neonates and in patients with impaired hepatic function.
 - Hypocalcaemia.
 - Hypoglycaemia.
 - Hypokalaemia.
- Immunological effects
 - Alloimmunisation to HLA and red cell antigens.
 - Graft vs Host Disease (GvHD) in immuno compromised recipients . The risk of GvHD is eliminated by irradiation
 - Transfusion related Acute Lung injury (TRALI) by donor HLA/granulocyte antibodies.
 - Post transfusion purpura (PTP).
- Iron overload
 - In patients on chronic red cell transfusion support programmes.

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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

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APPENDIX I

E Progesa Codabar Component Code: 54350

E Progesa ISBT – 128 Component Code : E8215V00

Product Name


WHOLE BLOOD, Suitable for
Neonatal Use for 5 Days after Date
Drawn. HCT Range: 0.50 – 0.60

Shelf life

28 days

Labelling and Barcode:

(for illustration purposes only – barcodes not suitable for scanning – label not to scale)





95A0

IBTS ver 5.0

**WHOLE BLOOD, Suitable for
Neonatal Use for 5 days after Date
Drawn. HCT Range: 0.50–0.60**


Store at 4°C ± 2°C






025129

Drawn 09 May 2025



E8215V00


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 66ml of CPD anticoagulant containing, in mmol/l:
Citric Acid 16, Sodium Citrate 89, Sodium Dihydrogen Phosphate 16, Glucose 129, Total Na Concentration 284.



54350


Rh D Negative

Confirmed Group
CMV Antibody Negative




0251572359

Expiry 06 June 2025 23:59




93999999999917796

C– E– c+ e+ K– HbS–Neg



Expiry 06/06/2025



O Neg

APPENDIX 1

E Progesa Codabar Component Code: 39360

E Progesa ISBT – 128 Component Code : E8212V00

Product Name

WHOLE BLOOD, Suitable for
Neonatal Use, Irradiated.
HCT Range: 0.50 – 0.60

Shelf life

24 hours

Labelling and Barcode:

(for illustration purposes only – barcodes not suitable for scanning – label not to scale)

IBTS ver 4.0

51F0

WHOLE BLOOD, Suitable for
Neonatal Use, Irradiated.
HCT Range: 0.50–0.60

Store at 4°C ± 2°C

025129

Drawn 09 May 2025

E8212V00

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 66ml of CPD anticoagulant containing, in mmol/l:

Citric Acid 16, Sodium Citrate 89, Sodium Dihydrogen Phosphate 16, Glucose 129, Total Na Concentration 284.

300 ml

0251301537

Expiry 10 May 2025 15:37

93999999999918496

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

39360

Expiry 10/05/2025

O Pos

Rh D Positive

CMV Antibody Negative
IRRADIATED (24 H)
Confirmed Group

APPENDIX II

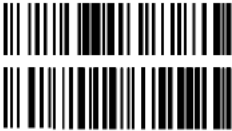
E Progesa Codabar Component Code: 39361

E Progesa ISBT – 128 Component Code : E8217V00

Product Name
WHOLE BLOOD, Suitable for
Neonatal Use for 5 Days after Date
Drawn. HCT Range: 0.50 – 0.55

Shelf life
28 days

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

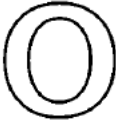


95A0


IBTS ver 4.0

WHOLE BLOOD, Suitable for
Neonatal Use for 5 days after Date
Drawn. HCT Range: 0.50–0.55

Store at 4°C ± 2°C




Rh D Negative
Confirmed Group
CMV Antibody Negative




025129

Drawn 09 May 2025



E8217V00

300 ml




0251572359

Expiry 06 June 2025 23:59

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 66ml of CPD anticoagulant containing, in mmol/l:

Citric Acid 16, Sodium Citrate 89, Sodium Dihydrogen Phosphate 16, Glucose 129, Total Na Concentration 284.




939999999199917796


C– E– c+ e+ K– Jkb– HbS–Neg



39361



Expiry 06/06/2025



O Neg

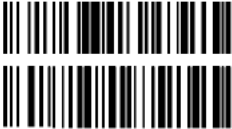
APPENDIX II

E Progesa Codabar Component Code: 39362

E Progesa ISBT – 128 Component Code : E8216V00

Product Name	Shelf life
WHOLE BLOOD, Suitable for Neonatal Use, Irradiated.	24 hours
HCT Range: 0.50 – 0.55	


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



51G0


IBTS ver 4.0

**WHOLE BLOOD, Suitable for Neonatal Use,
Irradiated**
HCT Range: 0.50 – 0.55
Store at 4°C ± 2°C




025129

Drawn 09 May 2025




E8216V00

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 66ml of CPD anticoagulant containing, in mmol/l:
Citric Acid 16, Sodium Citrate 89, Sodium Dihydrogen Phosphate 16, Glucose 129, Total Na Concentration 284.




39362



Rh D Positive


CMV Antibody Negative
IRRADIATED (24 H)
Confirmed Group

300 ml




0251301539

Expiry 10 May 2025 15:39




93995999999924796

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



Expiry 10/05/2025



O Pos