Irish Blood Transfusion Service
Seirbhís Fuilaistriúcháin na hÉireann

Document Detail

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Title: **LEUCOCYTES POOLED, RED CELL REDUCED, IRRADIATED, (SOURCE OF GRANULOCYTES)**
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Review

Review: IBTS PMF REVIEW

Level	Owner Role	Actor	Sign-off By
1	DOCUMENT CONTROLLER	REBECCA WALDEN	REBECCA WALDEN
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Change Orders

Changes as described on Change Order:	Change Order No.

Change Orders - Incorporated

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IRISH BLOOD TRANSFUSION SERVICE

PRODUCT MASTER FILE

TITLE: LEUCOCYTES POOLED, RED CELL REDUCED, IRRADIATED, (SOURCE OF GRANULOCYTES)

Change Description:
Revise IBTS/PMF/SPEC/0203 – 0218, 0220, 0221, 0224, 0226, 0227, 0232, 0236 to update the product labels in the appendices for each product.

Reason for Change:
Fix to the labels as part of the semester patch reference CC 126/19/IBTS and reference IBTS/QA/IQ/0600 Deviation 008

Change order No.:
IBTS/CO/0167/21

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: Leucocytes Pooled, Red Cell Reduced, Irradiated, (Source of Granulocytes)

Name of Product: LEUCOCYTES Pooled, Red Cell Reduced, Irradiated, (Source of Granulocytes)

E Progesa Codabar Component Code: 54264

E Progesa ISBT-128 Component Code: E8208V00

General Description: Leucocytes Pooled obtained by pooling up to 5 units of buffy coats derived from whole blood within 24 hours of venepuncture by centrifugation and automated separation. The selected donors meet the additional criteria for neonatal use. These pools contain granulocytes as a major cellular component suspended in anticoagulated blood. Red cell content is reduced by removal following centrifugation.

General Specification:

Parameter	Quality Requirement	Frequency of Control
Volume Range	44 - 62 ml per unit pooled	100 %
Leucocyte Content	1.6×10^9 per unit pooled	1%

Labelling: See Appendix I

Storage: Leucocytes Pooled, Red Cell Reduced, Irradiated, (Source of Granulocytes) should be used as soon as possible. If delay is unavoidable, the component should be stored at a core temperature of $22^oC \pm 2^oC$ without agitation and used within 24 hours.

Irradiation: Leucocytes Pooled, Red Cell Reduced, Irradiated, (Source of Granulocytes) **must** be irradiated **immediately** before issue.

Transportation: Transport containers should be kept open at room temperature for 30 minutes before use. During transportation from the Irish Blood Transfusion Service to the place where they are intended for use, the temperature of Leucocytes Pooled, Red Cell Reduced, Irradiated, (Source of Granulocytes) must be kept as close as possible to the recommended storage temperature. On receipt, if not transfused immediately, they should be transferred to storage at 22ºC ± 2ºC, unagitated.

Indications for Use: May be used in severely neutropenic patients with proven sepsis while receiving adequate antibiotic therapy.

Precautions in Use:

- As there is significant red cell contamination, compatibility testing is required.
- Leucocytes Pooled, Red Cell Reduced, Irradiated, (Source of Granulocytes) should be infused intravenously through a set containing an inline 170-200 µm filter.
- Leucocytes Pooled, Red Cell Reduced, Irradiated, (Source of Granulocytes) **must** be irradiated before transfusion.
- No solution should be added to the bag or giving set.
- Components should be inspected visually for defects, leakage, abnormal colour or visible clots.
- Rh D negative female recipients of child bearing potential should preferably not be transfused with Leucocytes Pooled, Red Cell Reduced, Irradiated, (Source of Granulocytes) from Rh D positive donors
- HLA alloimmunised recipients require HLA matched components if available.

Adverse Effects Include:

- Circulatory overload;
- Haemolytic transfusion reaction;
  - 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;
- Hypersensitivity reactions may occur but there is a reduced incidence of chills and fever;

- Non-haemolytic transfusion reactions may occur (namely fever, chills and urticaria);

- Anaphylaxis

- 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.

- 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 I

E Progesa Codabar Component Code : 54264

E Progesa ISBT -128 Component Code: E8208V00

Product Name
LEUCOCYTES Pooled,
Red Cell Reduced, Irradiated,
(Source of Granulocytes)

Shelf Life
24 hours

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