Irish Blood Transfusion Service
Seirbhís Fuilaistriúcháin na hÉireann

Document Detail

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Title: **RED CELLS, SUITABLE FOR INTRAUTERINE TRANSFUSION, IRRADIATED**
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Review

Review: IBTS PMF REVIEW

Level	Owner Role	Actor	Sign-off By
1	DOCUMENT CONTROLLER	REBECCA WALDEN	REBECCA WALDEN
2	QUALITY ASSURANCE WRITER IBTS	REBECCA WALDEN	REBECCA WALDEN
3	LABS HEAD OF MANUFACTURING & ISSUE IBTS	BARRY DOYLE	BARRY DOYLE
3	NATIONAL MEDICAL DIRECTOR	STEPHEN FIELD	STEPHEN FIELD
4	QUALITY ASSURANCE REVIEWER IBTS	COLIN JOHNS	COLIN JOHNS

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: RED CELLS, SUITABLE FOR INTRAUTERINE TRANSFUSION, IRRADIATED

Change Description:
Revise IBTS/PMF/SPEC/0203 to IBTS/PMF/SPEC/0212 and IBTS/PMF/SPEC/0232 to amend the product labels.

Reason for Change:
Fix to the labels with reference to IR 361/21/IBTS, IBTS/QA/PQ/0600 Deviation 012 and CC 134/21/IBTS

Change order No.:
IBTS/CO/0229/21

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: Red Cells, Suitable for Intrauterine Transfusion, Irradiated

Name of Product: **RED CELLS, Suitable for Intrauterine Transfusion, Irradiated HCT Range: 0.70 – 0.85**

E Progesa Codabar Component Code: **30017**

E Progesa ISBT – 128 Component Code : **E8210V00**

General Description: Red cells obtained from whole blood within 5 days of donation by centrifugation, and removal of most of the plasma. 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 Requirement	Frequent of Control
Volume	190-310 mL	100 %
Haematocrit	0.7 – 0.85	100 %
Haemoglobin	≥ 40 g / unit	100 %
Leucocyte Content	<1 x 10^6 / unit	Parent Component tested
ABO Agglutinins	No High Titre Anti-A or Anti-B	100%
CMV	CMV ab negative	100%

Labelling: See Appendix 1

Storage: Red Cells, Suitable for Intrauterine Transfusion, Irradiated should be used immediately. If delay is unavoidable, the component should be stored at 4°C ± 2°C and used within 24 hours from the time of preparation.

Irradiation: Red Cells, Suitable for Intrauterine Transfusion, Irradiated **must be irradiated** before transfusion. Post irradiation the storage is unchanged.

Transportation: The air temperature of transport containers for units of Red Cells, Suitable for Intrauterine Transfusion, Irradiated should be maintained between 2°C and 10°C during transportation between the Irish Blood Transfusion Service to the place that they are intended for use. Transport time under these conditions should not exceed 8 hours.

Indications for Use: Red Cells, Suitable for Intrauterine Transfusion, Irradiated are prepared, on request, for use in intra-uterine transfusion. Haematocrit may be adjusted to the required value prior to issue.

Precautions In Use:

- Compatibility of red cells with the intended recipient must be verified by suitable pre-transfusion testing.
- Red Cells, Suitable for Intrauterine Transfusion, Irradiated should be infused intravenously through a set containing an inline 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.

Adverse Effects Include:

- Circulatory Overload.
- Haemolytic transfusion reaction;
- Non-haemolytic transfusion reaction (mainly chills, fever and urticaria). The risk is reduced by leucodepletion
- Anaphylaxis

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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)
- 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
  - Alloimunisation 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.

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

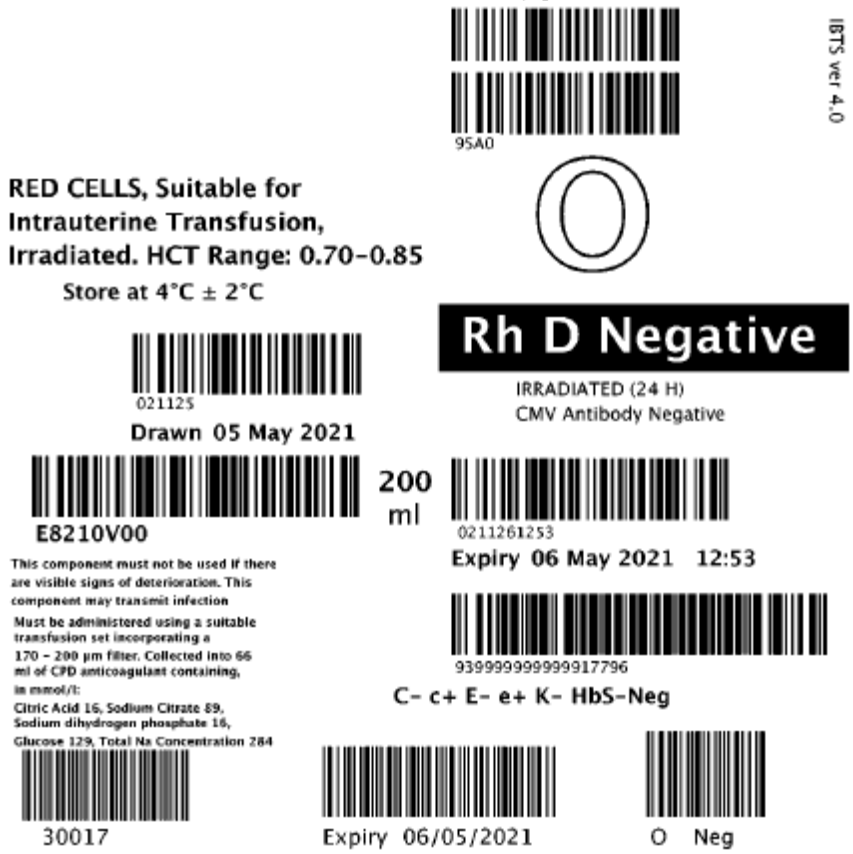
E Progesa Codabar Component Code : 30017

E Progesa ISBT -128 Code: E8210V00

Product Name
RED CELLS, Suitable for
Intrauterine Transfusion
Irradiated, HCT Range: 0.70 – 0.85

Shelf Life
24 hours

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



N.B. Stated volume for illustration purposes only.