Irish Blood Transfusion Service
Seirbhís Fuilaistriúcháin na hÉireann

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Review

Review: IBTS PMF REVIEW

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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: WHOLE BLOOD AUTOLOGOUS

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 Autologous**

Name of Product: **WHOLE BLOOD for Autologous Transfusion (CPDA1)**

E Progesa Codabar Component Code : **30002**

E Progesa ISBT-128 Component Code : **E4396100**

General Description: Unit of whole blood collected for the **sole purpose** of re-infusion into the donor, if required. The removal of the majority of leucocytes is achieved by filtration.

General Specification: Autologous donations shall be identified, collected, processed and verified as to quality according to Standard Operating Procedures for homologous blood donations.

Storage: Whole Blood, Leucodepleted for Autologous Transfusion should be stored at $4^{o}C \pm 2^{o}$ C. Autologous blood and blood components must be stored separately. The storage time is 35 days.

Labelling: See Appendix 1

Transportation: The air temperature of the validated transport containers for units of Whole Blood for autologous transfusion should be maintained between $2^{o}C$ and $10^{o}C$ during transport from the Irish Blood Transfusion Service to the place that they are intended for use. Transport time under these conditions normally should not exceed 8 hours.

Indications for Use:

- Whole blood for autologous transfusion can be used in selected elective surgical patients.
- Whole blood for autologous transfusion can also be considered for individuals with rare blood groups or with rare or multiple red cell antibodies.

Precautions in Use:

- Careful selection of appropriate patients is an important part of a safe and successful autologous pre-deposit programme.

- One or more venesections over a period of weeks may result in morbidity which needs to be balanced against the potential risks of receiving blood from volunteers.

- Careful attention to documentation is essential to reduce the risk of a clerical error which may lead to a haemolytic transfusion reaction.

- Pre-deposited blood should be transfused using similar clinical indications to those for allogeneic transfusion; it should not be transfused simply because it is available.

- Whole blood should be infused intravenously through a set containing an inline 170-200 µm filter.

Adverse Effects:

- Acute sepsis due to bacterial contamination.

- Autologous transfusions are also susceptible to adverse events such as acute haemolytic transfusion reactions that arise from errors in patient/recipient identification, and from failure to store the product within specified parameters.

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: 30002

E Progesa ISBT -128 Component Code: E4396100

Product Name:
WHOLE BLOOD for Autologous Transfusion (CPDA1)

Shelf Life:
35 days

Additional Tag containing the following data:

Side 1
Donor's name
Address
Date of Birth

Side 2
Unit Number
Name of admitting hospital
Donor's Signature
Medical Officer's Signature

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