Irish Blood Transfusion Service
Seirbhís Fuilaistriúcháin na hÉireann

Document Detail

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Title: **CRYOPRECIPITATE SUITABLE FOR NEONATAL USE**
Owner: QA DOC CON QA DOC CONTROL
Status CURRENT
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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 PHS DIR IBTS	BARRY DOYLE	BARRY DOYLE
3	NATIONAL MEDICAL DIRECTOR	STEPHEN FIELD	STEPHEN FIELD
4	QUALITY ASSURANCE REVIEWER IBTS	COLIN JOHNS	COLIN JOHNS

Review: IBTS DOC PERIODIC REVIEW

Level	Owner Role	Actor	Sign-off By
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2	QUALITY ASSURANCE WRITER IBTS	REBECCA WALDEN	REBECCA WALDEN
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4	QUALITY ASSURANCE REVIEWER IBTS	COLIN JOHNS	COLIN JOHNS
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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/0167/21

Valid on Day of Printing, Verify Current Version
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IRISH BLOOD TRANSFUSION SERVICE

PRODUCT MASTER FILE

TITLE: CRYOPRECIPITATE SUITABLE FOR NEONATAL USE

Verify when in Use. Status CURRENT Effective 18 April 2021

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
BT - 0457

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: **Cryoprecipitate Suitable for Neonatal Use**

Name of Product: **CRYOPRECIPITATE, Suitable for Neonatal Use**

E Progesa Codabar Component Code : **80160**

E Progesa ISBT-128 Component Code : **C6296V00**

General Description: Cryoprecipitate, Suitable for Neonatal use contains the major portion of Factor VIIIc, von Willebrand factor, fibrinogen, Factor XIII and fibronectin from a unit of Fresh Frozen Plasma. The selected donors meet the additional criteria for neonatal use. Prepared from male donors only. The parent donation is filtered as whole blood.

Verify when in Use. Status CURRENT Effective 6 April 2021

General Specification:

Parameter	Quality Requirement	Frequency of Control
Volume	30 - 40 ml	100 %
Factor VIIIc	> 70 IU/unit	1%
Fibrinogen	>140 mg/unit	1%
Von Willebrand Factor	>100 IU/unit	1%
ABO Agglutinins	No HighTitre Anti-A or Anti-B	100%
CMV	CMV ab negative	100%

Labelling: See Appendices I and II.

Storage: Cryoprecipitate should be stored at a core temperature of ≤ - 25°C, for a maximum of 12 months. Once thawed, the component must not be refrozen and should be used immediately. If delay is unavoidable, the component should be stored at ambient temperature and used within 6 hours.

Transportation: The air temperature of the transport container for Cryoprecipitate should be maintained ≤ - 25°C during transportation from The Irish Blood Transfusion Service to the place intended for use. Unless Cryoprecipitate is to be thawed for immediate therapeutic use, it should be transferred immediately to storage at ≤ - 25°C.

Indications for Use: Quantitative and Qualitative disorders of fibrinogen such as acquired hypofibrinogenaemia in disseminated intravascular coagulopathy and following large volume transfusion.

Verify when in Use. Status CURRENT Effective 1 April 2021

Precautions In Use:

- Cryoprecipitate should be thawed in a properly controlled environment at 37°C immediately after removal from storage and immediately before use. Dissolving of the precipitate should be encouraged by careful manipulation during the thawing procedure. The integrity of the pack should be verified to exclude any defects or leakage.
- Cryoprecipitate should not be refrozen.
- Cryoprecipitate should be infused intravenously through a set containing an inline 170-200 µm filter.

Adverse Effects Include:

- Haemolytic transfusion reaction due to transfusion of ABO-incompatible plasma in the component.
- Non Haemolytic transfusion reactions - chills, fever, hypersensitivity.
- Metabolic upset
  - Citrate toxicity in patients with impaired hepatic function or where large volumes are rapidly transfused.
- Immunological effects
  - Alloimunisation to HLA and HPA antigens
  - Transfusion related Acute Lung injury (TRALI) by donor HLA/granulocyte antibodies
- 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)

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 18 April 2021

APPENDIX I

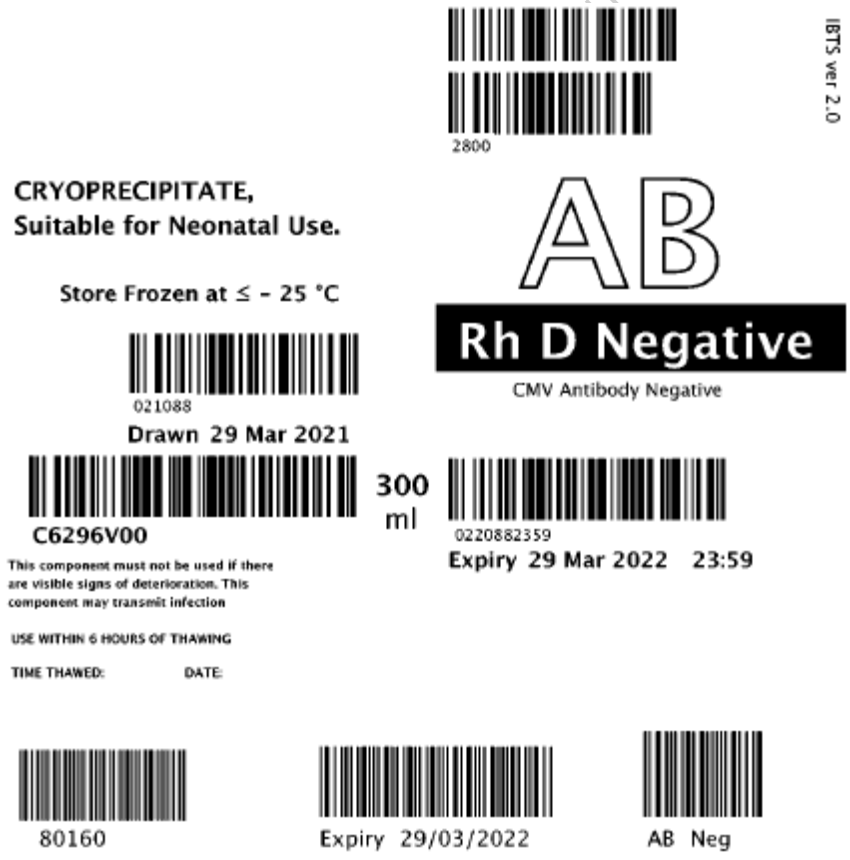
E Progesa Codabar Component Code: 80160

E Progesa ISBT -128 Component Code: C6296V00

Effective 18 April 2021

Product Name	**Shelf Life**
CRYOPRECIPITATE, Suitable for Neonatal Use	365 days

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



N.B. Stated volume for illustration purposes only.

APPENDIX II

BT - 0457

Irish Blood Transfusion Service
Seirbhís Fuilaistriúcháin na hÉireann

CRYOPRECIPITATE SUITABLE FOR NEONATAL USE

National Blood Centre,
James's St,
Dublin 8
Tel. (01) 4322800

Munster Regional Transfusion Centre
St. Finbarr's Hospital
Cork
Tel. (021) 4807400

Storage: Store the cryoprecipitate depleted plasma in this container at ≤ -25°C.

Thawing: Place the component within its plastic overwrap in a 37°C temperature controlled dedicated water bath or remove the overwrap and place in a validated microwave plasma defroster until thawed. Dissolution of the precipitate should be encouraged by careful manipulation during thawing. Remove from waterbath or microwave plasma defroster, mix gently by inversion and check for precipitate.

IMPORTANT: ONCE THAWED CRYOPRECIPITATE SHOULD BE INFUSED WITHOUT DELAY BUT NOT LATER THAN SIX HOURS AFTER THAWING. THE THAWED CRYOPRECIPITATE SHOULD BE HELD AT AMBIENT TEMPERATURE.

UNDER NO CIRCUMSTANCES MAY THAWED CRYOPRECIPITATE BE REFROZEN

Warning: CRYOPRECIPITATE MUST NOT BE USED IF THERE ARE VISIBLE SIGNS OF DETERIORATION. THIS COMPONENT MAY TRANSMIT INFECTION.

August 2015

Verify when in use Status CURRENT