



Irish Blood Transfusion Service

Seirbhís Fuilaeistriúcháin na hÉireann

Document Detail

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Title: **PLATELETS, HYPERCONCENTRATED, SUITABLE FOR
NEONATAL USE, IRRADIATED**
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Review

Review: IBTS PMF REVIEW

<u>Level</u>	<u>Owner Role</u>	<u>Actor</u>	<u>Sign-off By</u>
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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

IRISH BLOOD TRANSFUSION SERVICE
PRODUCT MASTER FILE

TITLE: **HYPERCONCENTRATED, SUITABLE FOR NEONATAL USE, IRRADIATED**

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: Platelets, Hyperconcentrated, Suitable for Neonatal Use, Irradiated****Name of Products:****PLATELETS, Hyperconcentrated, Suitable for Neonatal Use, Irradiated****PLATELETS, Hyperconcentrated, Suitable for Neonatal Use, Split 1, Irradiated****PLATELETS, Hyperconcentrated, Suitable for Neonatal Use, Split 2, Irradiated****PLATELETS, Hyperconcentrated, Suitable for Neonatal Use, Split 3, Irradiated****E Progesa Codabar Component Codes: 39310 / 39311 / 39312 / 39313.****E Progesa ISBT-128 Component Codes: C9310V00 / C9310VA0 / C9310VB0 / C9310VC0.**

General Description: A platelet preparation with the majority of leucocytes removed, suspended in plasma obtained from a single donor using automated cell separation equipment. The removal of part of the plasma is achieved by centrifugation. The selected donors meet the additional criteria for neonatal use.

General Specification:

Parameter	Quality Requirement	Frequency of Control
Volume	100 ml +/- 20 ml	100%
Platelet Content	$\geq 200 \times 10^9$ / unit	100 %
Leucocyte Content	$< 1 \times 10^6$ / unit	100 % (Parent Component tested)
pH measured (+22°C) at the end of the recommended shelf-life	> 6.4	4 per annum.

Labelling: See Appendix 1

- Storage :** Platelets, Hyperconcentrated, Suitable for Neonatal Use, Irradiated should be used immediately. If delay is unavoidable, platelets should be stored with continuous gentle agitation at $22^{\circ}\text{C} \pm 2^{\circ}\text{C}$ and used within 6 hours of preparation.
- Irradiation:** Platelets are irradiated routinely during preparation.
- 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 platelets must be kept as close as possible to the recommended storage temperature. On receipt, if not transfused immediately, they should be transferred to storage with continuous gentle agitation on a device approved for the purpose, at $22^{\circ}\text{C} \pm 2^{\circ}\text{C}$.
- Indications for Use:** To provide platelet replacement where deficiency or functional abnormality is causing significant haemostatic problems.
- Precautions in Use:**
- Swirling phenomenon must be demonstrated before infusion.
 - Platelets, Hyperconcentrated, Suitable for Neonatal Use, Irradiated must be infused intravenously through a fresh infusion set containing an in-line 170 – 200 μm filter.
 - Rh D negative female recipients of child bearing potential should preferably not be transfused with platelets from Rh D positive donors.
 - Because of the temperature of storage and preparation the risk of bacterial contamination is increased.
 - No solution should be added to the bag or giving set.
 - Components should be inspected visually for defects, leakage, abnormal colour or visible clots.
 - Not recommended in cases of plasma intolerance.
- Adverse Effects Include:**
- Circulatory overload
 - Haemolytic transfusion reaction due to transfusion of ABO-incompatible plasma in the component.
 - Non-haemolytic transfusion reaction (mainly chills, fever and urticaria). The risk is reduced by leucodepletion.
 - 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)
- Metabolic upset
 - Citrate toxicity, especially in neonates and in patients with impaired hepatic function.
- Immunological effects
 - Alloimmunisation to HLA and HPA antigens
 - Post Transfusion purpura (PTP), especially in parous female recipients
 - The risk of Graft vs Host Disease (GvHD) in immuno compromised recipients is eliminated by irradiation
 - Transfusion related Acute Lung injury (TRALI) by donor HLA/granulocyte antibodies

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: 39310

E Progesa ISBT-128 Component Code : C9310V00

Product Name :
PLATELETS, Hyperconcentrated,
Suitable for Neonatal Use,
Irradiated

Shelf Life :
6 hours.

Product Label and Barcode:

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

PLATELETS, Hyperconcentrated,
Suitable for Neonatal Use,
Irradiated

Store at 22°C ± 2°C



021088

Drawn 29 Mar 2021



C9310V00

This component must not be used if there are visible signs of deterioration. This component may transmit infection

AGITATE GENTLY THROUGHOUT STORAGE
Must be administered using a suitable transfusion set incorporating a 170 – 200 µm filter.



9500



Rh D Negative

CMV Antibody Negative

300
ml



0210882028

Expiry 29 Mar 2021 20:28



39310



Expiry 29/03/2021



O Neg

APPENDIX I

E Progesa Codabar Component Code: 39311

E Progesa ISBT-128 Component Code : C9310VA0

Product Name :
PLATELETS, Hyperconcentrated,
Suitable for Neonatal Use,
Split 1, Irradiated

Shelf Life :
6 hours.

Product Label and Barcode:

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

9500

IBTS ver 2.0

PLATELETS, Hyperconcentrated,
Suitable for Neonatal Use,
Split 1, Irradiated
Store at 22°C ± 2°C

021088

Drawn 29 Mar 2021

300 ml

C9310VA0

This component must not be used if there are visible signs of deterioration. This component may transmit infection
AGITATE GENTLY THROUGHOUT STORAGE
Must be administered using a suitable transfusion set incorporating a 170 – 200 µm filter.

Rh D Negative
CMV Antibody Negative

0210882028

Expiry 29 Mar 2021 20:28



39311



Expiry 29/03/2021



O Neg

APPENDIX I

E Progesa Codabar Component Code: 39312

E Progesa ISBT-128 Component Code : C9310VB0

Product Name :
PLATELETS, Hyperconcentrated,
Suitable for Neonatal Use,
Split 2, Irradiated

Shelf Life :
6 hours.

Product Label and Barcode:

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

IBTS ver 2.0

9500

PLATELETS, Hyperconcentrated,
Suitable for Neonatal Use,
Split 2, Irradiated
Store at 22°C ± 2°C

021088

Drawn 29 Mar 2021

300 ml

C9310VB0

0210882029

Expiry 29 Mar 2021 20:29

This component must not be used if there are visible signs of deterioration. This component may transmit infection. AGITATE GENTLY THROUGHOUT STORAGE. Must be administered using a suitable transfusion set incorporating a 170 – 200 µm filter.

Rh D Negative
CMV Antibody Negative



39312



Expiry 29/03/2021



O Neg

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APPENDIX I

E Progesa Codabar Component Code: 39313

E Progesa ISBT-128 Component Code : C9310VC0

Product Name :
PLATELETS, Hyperconcentrated,
Suitable for Neonatal Use,
Split 3, Irradiated

Shelf Life :
6 hours.

Product Label and Barcode:

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

IBTS ver 2.0

9500

**PLATELETS, Hyperconcentrated,
Suitable for Neonatal Use,
Split 3, Irradiated**

Store at 22°C ± 2°C

Rh D Negative

CMV Antibody Negative

021088

Drawn 29 Mar 2021

300 ml

C9310VC0

0210882029

Expiry 29 Mar 2021 20:29

This component must not be used if there are visible signs of deterioration. This component may transmit infection

AGITATE GENTLY THROUGHOUT STORAGE

Must be administered using a suitable transfusion set incorporating a 170 – 200 µm filter.

39313

Expiry 29/03/2021

O Neg

N.B. Stated volume for illustration purposes only.