



Irish Blood Transfusion Service

Seirbhís Fuilaidriúcháin na hÉireann

Document Detail

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Title: **PLATELETS SUITABLE FOR NEONATAL USE**
Owner: 1066 KATE FITZGERALD
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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/0334/15

**IRISH BLOOD TRANSFUSION SERVICE
PRODUCT MASTER FILE**

Title : Platelets Suitable for Neonatal Use

Name of Products:

PLATELETS, Adult Dose, Suitable for Neonatal Use, Irradiated.

PLATELETS, Adult Dose, Suitable for Neonatal Use, Split 1/2/3, Irradiated.

These products can be extended into the following:

PLATELETS, Adult Dose, Suitable for Neonatal Use, Irradiated.

PLATELETS, Adult Dose, Suitable for Neonatal Use, Split 1/2/3, Irradiated,

An aliquot can be taken from any component above to make the following:

PLATELETS, Paediatric Dose, Suitable for Neonatal Use, Split 1/2/3, Irradiated,

E Progesa Codabar Component Codes: 39300 / 39301 / 39304 / 39307

77170 / 77171 / 77174 / 77177

39303 / 39306 / 39309.

E Progesa ISBT-128 Component Codes : C3929V00 / C3929VA0 / C3929VB0 / C3929VC0

C7716V00 / C7716VA0 / C7716VB0 / C7716VC0

C3929VAa / C3929VBa / C3929VCa.

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 selected donors meet the additional criteria for neonatal use.

General Specification:

Parameter	Quality Requirement	Frequency of Control
Volume	>40 ml per 60×10^9 platelets	100 %
Platelet Content	$\geq 200 \times 10^9$ / unit	100 %
Leucocyte Content	$< 1 \times 10^6$ / unit	100 %
pH measured (+22°C) at the end of the recommended shelf-life	>6.4	1%

- Labelling:** See Appendices I, II and III
- Storage:** Platelets should be stored at $22^{\circ}\text{C} \pm 2^{\circ}\text{C}$. The storage time is 5 days when stored with continuous gentle agitation. The storage time may be extended to 7 days if a bacterial screen test is performed on day 4. An aliquot may be removed for which the storage time is 6 hours. The storage time of the parent product is unchanged.. If extended the component codes then change to **77170 / 77171 / 77174 / 77177 / C7716V00 / C7716VA0 / C7716VB0 / C7716VC0**.
- 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, unless intended for immediate therapeutic use, 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 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 reduced by leucocyte depletion.
 - Acute Sepsis due to bacterial contamination is reduced 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

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

St Finbarr's Hospital
Douglas Road
Cork.

APPENDIX I

E Progesa Codabar Component Code: 39300

E Progesa ISBT-128 Component Code : C3929V00

Product Name :
PLATELETS, Adult Dose, Suitable
for Neonatal Use, Irradiated

Shelf Life :
5 days.

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

IBTS ver 1.0

5100

**PLATELETS, Adult Dose, Suitable
for Neonatal Use, Irradiated**

Store at 22°C ± 2°C

015204
Drawn 23 July 2015

230
ml

C3929V00

0152092359
Expiry 28 July 2015 23:59

O

Rh D Positive

CMV Antibody Negative
IRRADIATED

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.

39300 Expiry 28/07/2015 O Pos

APPENDIX I

E Progesa Codabar Component Code: 39301

E Progesa ISBT-128 Component Code : C3929VA0

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

Shelf Life :
5 days.

Product Label and Barcode:

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

IBTS ver 1.0

**PLATELETS, Adult Dose,
Suitable for Neonatal Use,
Split 1, Irradiated.**

Store at 22°C ± 2°C

O

Rh D Positive

CMV Antibody Negative
IRRADIATED

230 ml

Expiry 28 July 2015 23:59

Drawn 23 July 2015

C3929VA0

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.

39301 Expiry 28/07/2015 O Pos

APPENDIX I

E Progesa Codabar Component Code: 39304

E Progesa ISBT-128 Component Code : C3929VB0

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

Shelf Life :
5 days.

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

IBTS ver 1.0

PLATELETS, Adult Dose,
Suitable for Neonatal Use,
Split 2, Irradiated

Store at 22°C ± 2°C

015204
Drawn 23 July 2015

C3929VB0

230 ml

0152092359
Expiry 28 July 2015 23:59

O

Rh D Positive

CMV Antibody Negative
IRRADIATED

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.

39304

Expiry 28/07/2015

O Pos

APPENDIX I

E Progesa Codabar Component Code: 39307

E Progesa ISBT-128 Component Code : C3929VC0

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

Shelf Life :
5 days.

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

IBTS ver 1.0

PLATELETS, Adult Dose,
Suitable for Neonatal Use,
Split 3, Irradiated.

Store at 22°C ± 2°C

015204
Drawn 23 July 2015

230 ml

C3929VC0

0152092359
Expiry 28 July 2015 23:59

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.

39307

Expiry 28/07/2015

O Pos

Rh D Positive

CMV Antibody Negative
IRRADIATED

APPENDIX II

E Progesa Codabar Component Code : 77170

E Progesa ISBT-128 Component Code : C7716V00

Product Name:
PLATELETS, Adult Dose,
Suitable for Neonatal Use,
Irradiated

Shelf Life:
7 days.

Product Label and Barcode:

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

IBTS ver 1.0

9500

**PLATELETS, Adult Dose,
Suitable for Neonatal Use,
Irradiated**

Store at 22°C ± 2°C

015204

Drawn 23 July 2015

230 ml

0152112359

C7716V00

Rh D Negative

CMV Antibody Negative
IRRADIATED

Expiry 30 July 2015 23:59

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.

77170

Expiry 30/07/2015

O Neg

APPENDIX II

E Progesa Codabar Component Code : 77171

E Progesa ISBT-128 Code : C7716VA0

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

Shelf Life:
7 days.

Product Label and Barcode:

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

IBTS Ver 1.0

9500

**PLATELETS, Adult Dose,
Suitable for Neonatal Use,
Split 1, Irradiated**

Store at 22°C ± 2°C

015204

Drawn 23 July 2015

Rh D Negative

CMV Antibody Negative
IRRADIATED

230 ml

0152112359

Expiry 30 July 2015 23:59

C7716VA0

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.

77171

Expiry 30/07/2015

O Neg

APPENDIX II

E Progesa Codabar Component Code : 77174

E Progesa ISBT-128 Component Code : C7716VB0

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

Shelf Life:
7 days.

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

IBTS ver 1.0

9500

**PLATELETS, Adult Dose,
Suitable for Neonatal Use,
Split 2, Irradiated**

Store at 22°C ± 2°C

015204

Drawn 23 July 2015

230 ml

C7716VB0

Rh D Negative

CMV Antibody Negative
IRRADIATED

0152112359

Expiry 30 July 2015 23:59

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.

77174

Expiry 30/07/2015

O Neg

APPENDIX II

E Progesa Codabar Component Code : 77177

E Progesa ISBT-128 Component Code : C7716VC0

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

Shelf Life:
7 days.

Product Label and Barcode:

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

IBTS ver 1.0

9500

PLATELETS, Adult Dose,
Suitable for Neonatal Use,
Split 3, Irradiated

Store at 22°C ± 2°C

015204

Drawn 23 July 2015

C7716VC0

0 ml

0152112359

Expiry 30 July 2015 23:59

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
IRRADIATED

77177

Expiry 30/07/2015

O Neg

APPENDIX III

E Progesa Codabar Component Code : 39303

E Progesa ISBT-128 Component Code : C3929VAa

Product Name :
PLATELETS, Paediatric Dose,
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)

IBTS ver 1.0

3100

PLATELETS, Paediatric Dose,
Suitable for Neonatal Use,
Split 1, Irradiated

Store at 22°C ± 2°C

015294

Drawn 23 July 2015

60 ml

C3929VAa

O

Rh D Positive

CMV Antibody Negative
IRRADIATED

0152092308

Expiry 28 July 2015 23:08

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.

39303

Expiry 28/07/2015

O Pos

APPENDIX III

E Progesa Codabar Component Code : 39306

E Progesa ISBT-128 Component Code: C3929VBa

Product Name :
PLATELETS, Paediatric Dose,
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 1.0

PLATELETS, Paediatric Dose,
Suitable for Neonatal Use,
Split 2, Irradiated

Store at 22°C ± 2°C

015204
Drawn 23 July 2015

60 ml

C3929VBa

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.

O

Rh D Positive

CMV Antibody Negative
IRRADIATED

0152092314
Expiry 28 July 2015 23:14

39306

Expiry 28/07/2015

O Pos

APPENDIX III

E Progesa Codabar Component Code : 39309

E Progesa ISBT-128 Component Code : C3929VCa

Product Name :

PLATELETS, Paediatric Dose,
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 1.0

3100

3100

PLATELETS, Paediatric Dose,
Suitable for Neonatal Use,
Split 3, Irradiated

Store at 22°C ± 2°C

015204

Drawn 23 July 2015

50 ml

C3929VCa

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.

0152092318

Expiry 28 July 2015 23:18

39309

Expiry 28/07/2015

O Pos