



Irish Blood Transfusion Service

Seirbhís Fuilaidriúcháin na hÉireann

Document Detail

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Title: **PLATELETS, ADULT DOSE WITH PLASMA / PAS, WASHED, IRRADIATED**
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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

Changes as described on Change Order: Change Order No.
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**IRISH BLOOD TRANSFUSION SERVICE
PRODUCT MASTER FILE**

TITLE: PLATELETS, ADULT DOSE WITH PLASMA / PAS, WASHED, IRRADIATED

Name of Product:

- **PLATELETS, Adult Dose with Plasma / PAS, Washed, Irradiated**

E Progesa Codabar Component Code: 69741

E Progesa ISBT – 128 Component Code: E7546V00.

General Description: Platelets prepared from a pool of four buffy coats suspended in approximately 65% additive solution and 35% plasma subsequently washed and resuspended in isotonic saline. The removal of the majority of leucocytes is achieved by filtration.

General Specification:

| Parameter | Quality Requirements | Frequency of Control |
|------------------|-------------------------------|-----------------------------|
| Volume | 180 - 220 ml / unit | 100% |
| Platelet Content | $\geq 160 \times 10^9$ / unit | 100% |
| Protein Content | < 0.5g / unit | 4 per year |

Labelling: See Appendix 1

Storage: Platelets Adult Dose with Plasma / PAS, Washed, 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, in patients with significant reactions to plasma. Platelets Adult Dose with Plasma / PAS, Washed, Irradiated (protein content $< 0.5\text{mg/unit}$) are not designated for the transfusion of patients with IgA deficiency.

Precautions in Use:

- Swirling phenomenon should 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.

Adverse Effects Include:

- Circulatory overload
- Non-haemolytic transfusion reaction (mainly chills, fever and urticaria). The risk is reduced by leucodepletion and by the removal of cytokines present in the donor plasma.
- 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.
- 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. This risk is reduced by the removal of donor plasma

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:

69741

E Progesa ISBT-128 Component Code :

E7546V00

Product Name:PLATELETS, Adult Dose with
Plasma / PAS, Washed, Irradiated**Shelf Life:**

6 hours

Product Label and Barcode:

(for illustration purposes only – barcodes not suitable for scanning)

IBTS ver 1.0

9500

PLATELETS, Adult Dose with
Plasma/PAS, Washed, Irradiated

Store at 22°C ± 2°C

017164

Drawn 13 June 2017

196 ml

E7546V00

0171641808

Expiry 13 June 2017 18:08

Rh D Negative

Units in pool: 4

69741

Expiry 13/06/2017

O Neg

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. Washed and suspended in isotonic saline solution containing, in mmol/l: NaCl 75 - 150.