Irish Blood Transfusion Service
Seirbhís Fuilaistriúcháin na hÉireann

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Review: IBTS DOC PERIODIC REVIEW

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IRISH BLOOD TRANSFUSION SERVICE

PRODUCT FILE

Name of Product: **Fresh Frozen CONVALESCENT PLASMA COVID-19**

General Description: Plasma obtained from a unit of whole blood from donors who have recovered from COVID-19 infection, rapidly frozen to a temperature that adequately maintains the proteins in a functional state. The majority of leucocytes are removed by filtration. Prepared from male regular donors only. Suitable for adult use where the intended recipient has laboratory confirmed COVID-19 infection and has evidence of immunosuppression and B-cell depletion, is on active treatment for any type of cancer or has history of haematological cancer treated in the past.

Codabar Component Code: 97490

ISBT-128 Component Code : E9749V00

General Specification:

Parameter	Quality Requirement	Frequency of Control
Volume	≥ 220 ml	100%*
Factor VIIIc	Not less than 0.7 iu/ml	10 per 3 months
Platelet Content	< 30 x 10^9/l	4 per month
Leucocyte Content	< 1 x 10^6/unit	4 per month
Red Cell presence	Absent when examined macroscopically	100 %
Total Protein	≥50g/L	10 per 3 months
Anti-SARS-CoV-2 antibodies	Must meet the current FDA qualification criteria	100%

*Visual inspection at time of labelling

Labelling: See Appendix 1

Storage: The shelf life of Convalescent Plasma COVID-19 is dependent on the core storage temperature as follows:

36 months if stored at ≤ -25°C
3 months if stored at -18°C to -25°C

Once thawed, Convalescent Plasma COVID-19 must not be refrozen and should be used immediately. If delay is unavoidable, the thawed product should be used as follows:

Within 24 hours if stored at +4°C ±2°C
Within 4 hours if stored at +22°C ±2°C

Thawing: Place in a 37°C controlled dedicated waterbath in the plastic overwrap or by removing the overwrap and placing in a dedicated, validated thawing device until the Convalescent Plasma COVID-19 is thawed.

Transportation: The air temperature of the transport container for units of Convalescent Plasma COVID-19 must be maintained during transportation from the Irish Blood Transfusion Service to the place that they are intended for use. Unless the Convalescent Plasma COVID-19 is to be thawed for immediate therapeutic use, it must be transferred immediately to storage at the recommended temperature.

Indications for Use: Convalescent Plasma COVID-19 may be used in the treatment of selected COVID-19 patients, specifically patients with any type of cancer on active treatment, patients with current or history of haematological cancer and immunocompromised patients with B-cell depletion.

Convalescent Plasma COVID-19 **must not** be used simply to correct a volume deficit in the absence of acute respiratory symptoms in COVID-19 patients.

Precautions for Use:

- Convalescent Plasma COVID-19 must be infused intravenously through a set containing an in line 170-200 µm filter.
- Convalescent Plasma COVID-19 must not be used in a patient with intolerance to plasma proteins.

- ABO blood group compatible Convalescent Plasma COVID-19 should be used and where possible, women of child bearing age and younger should receive Rh D compatible plasma.

- Before use the component must be thawed as described above and the integrity of the pack must be verified to exclude any defects or leakages. No insoluble particulate matter should be visible on completion of the thawing procedure.

- No solution should be added to the bag or giving set.

Adverse Effects Include:

- Transfusion Associated Circulatory Overload (TACO)

- Haemolytic transfusion reaction due to transfusion of ABO-incompatible plasma in the component.

- Non Haemolytic transfusion reactions - chills, fever, hypersensitivity.

- Anaphylaxis

- 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, viral transmission may, in rare instances, occur.
  -vCJD transmission
  -Transmission of other pathogens that are not tested for or recognised.
  -Acute sepsis due to bacterial contamination

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
D08 NH5R

AND

National Quality Assurance Manager
Irish Blood Transfusion Service
National Blood Centre
James's Street
Dublin 8
D08 NH5R

OR

Medical Department
Munster Regional Transfusion Centre
St Finbarr's Hospital
Douglas Road
Cork.
T12 Y312

APPENDIX 1

Product Name **Fresh Frozen CONVALESCENT PLASMA COVID-19**

E Progesa Codabar Component Code : **97490**

E Progesa ISBT -128 Component Code: **E9749V00**

Shelf Life (Frozen) 36 months if stored at ≤ -25°C
3 months if stored at -18°C to -25°C

Shelf Life (Thawed) 24 hours if stored at +4°C ±2°C
4 hours if stored at +22°C ±2°C

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