COVID-19 Convalescent Plasma Product Information Sheet

Parent document: SOP-01209

Important Note: This Product Information Sheet provides product-specific information about **COVID-19 Convalescent Plasma** and must be read in conjunction with the Australian Red Cross Blood Service *Blood Component Information: An Extension of Blood Component Labels, June 2019.* [1] (Available at www.transfusion.com.au)

Blood Component Information: An Extension of Blood Component Labels, June 2019 provides information regarding:

- Blood donor selection and collection of blood
- Testing of donor blood
- Processing blood into components
- Blood component therapy
- Blood component labelling
- Storage, transport and handling
- Administration methods
- Adverse reactions
- Additives and anticoagulants

COVID-19 CONVALESCENT PLASMA	
Description	COVID-19 CONVALESCENT PLASMA is a clinical fresh frozen plasma (FFP) component collected from a donor who has recovered from Coronavirus Disease 2019 (COVID-19) and has produced antibodies to the virus.[2,3,4] COVID-19 CONVALESCENT PLASMA is either separated from a single unit of whole blood or collected by apheresis where the plasma is retained and the remaining elements are returned to the donor. Apheresis-derived COVID-19 CONVALESCENT PLASMA may be split into 2 or 3 units of equal volume prior to freezing. Freezing of whole blood plasma must commence within 18 hours of collection and freezing of apheresis plasma must commence within six hours of collection. Contains neutralising antibodies against COVID-19 and all coagulation factors including approximately 200 IU of Factor VIII plus the other labile plasma coagulation factor, Factor V.
Indications	For use in approved clinical trials investigating the use of convalescent plasma as a treatment for patients with symptomatic COVID-19. Contact Lifeblood for information relating to the approved trials.
Contraindications	Do not use COVID-19 CONVALESCENT PLASMA outside of the clinical trial setting.
Specification	COVID-19 neutralising antibody titre ≥ 1 in 80.
Other typical unit content Data from 1 January 2018 to 31 December 2018	**WHOLE BLOOD DERIVED** **Parameter** / **Mean (± 1 SD)** / **Specification** Volume (mL) / 278 ± 13 / 250-310 FVIIIc (IU/mL) / 1.09 ± 0.19 / ≥ 0.70 **APHERESIS DERIVED** **Parameter** / **Mean (± 1 SD)** / **Specification** Volume (mL) / 271 ± 8 / 250-310 FVIIIc (IU/mL) / 1.24 ± 0.15 / ≥ 0.70

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Availability	Contact local Lifeblood centre regarding availability.
Shelf life	12 months.
Storage temperature	-25 °C or below.
Dosage	As per the relevant clinical trial protocol.
Administration	Thaw using an approved method. Refer to *Blood Component Information 2019* Storage, transport and handling (page 15).[1] Once thawed, should be transfused as soon as practicable. Mix thoroughly by inversion before use and transfuse through an intravenous line approved for blood administration which incorporates a standard (170–200 µm) filter. Transfusion of each unit may proceed as fast as tolerated but should be completed within 4 hours of removal from approved controlled storage.
Adverse reactions	Refer to *Blood Component Information 2019* Appendix IV: Transfusion reactions (pages 49-66).[1]
Modifications	Low anti-A/B. Refer to *Blood Component Information 2019* Appendix III: Explanation of Blood Component Label Modifier Text (page 48).[1]
Comments	Compatibility tests before transfusion are not necessary. Plasma should be ABO compatible with the recipient's red cells. Group O plasma should be restricted to group O recipients. Plasma components that have low titre anti-A or anti-B pose a lower risk of haemolysis when transfusing ABO incompatible components. Group AB plasma products, although suitable for patients of all ABO groups, are often in short supply. Group A plasma products may be used for adults as an alternative to group AB (unless the product is known to have high-titre anti-B). Matching for RhD type is not necessary.

References

1. Australian Red Cross Blood Service. *Blood Component Information: An Extension of Blood Component Labels, June 2019*. Australian Red Cross Blood Service, 2019. (Available at www.transfusion.com.au)
2. Mair-Jenkins J, Saavedra-Campos M, Baillie JK et al. *The Effectiveness of Convalescent Plasma and Hyperimmune Immunoglobulin for the Treatment of Severe Acute Respiratory Infections of Viral Etiology: A Systematic Review and Exploratory Meta-analysis.* J Infect Dis. 2015;211(1):80-90.
3. United States Food and Drug Administration. *Recommendations for Investigational COVID-19 Convalescent Plasma.* 1 May 2020. (Available at https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/investigational-covid-19-convalescent-plasma-emergency-inds)
4. Duan K, Bende L Ceshang L et al. *Effectiveness of Convalescent Plasma Therapy in Severe COVID-19 Patients. PNAS* April 2020 DOI: 10.1073/pnas.2004168117.