

Coding Information

INTERCEPT[®] Pathogen Reduced Cryoprecipitated Fibrinogen Complex (INTERCEPT[®] Fibrinogen Complex) and INTERCEPT[®] Pathogen Reduced Plasma,

Cryoprecipitate Reduced

Coding

BloodHub Ordering Information

These are the codes to use when ordering from BloodHub (<u>https://cerus.bloodhub.com/</u>).

Product Type	Catalog #	Description*
INTERCEPT Fibrinogen Complex	FC10	EA489 - Pooled Fibrinogen Complex 1.0, Cryoprecipitated, Psoralen Treated - 740 mg Fibrinogen (mean)
	FC15	EA490 - Pooled Fibrinogen Complex 1.5, Cryoprecipitated, Psoralen Treated - 1,457 mg Fibrinogen (mean)
	FC20	EA491 - Pooled Fibrinogen Complex 2.0, Cryoprecipitated, Psoralen Treated - 2,220 mg** Fibrinogen (mean)
	FC30	EA492 - Pooled Fibrinogen Complex 3.0, Cryoprecipitated, Psoralen Treated - 3,117 mg Fibrinogen (mean)
	FC40	EA493 - Pooled Fibrinogen Complex 4.0, Cryoprecipitated, Psoralen Treated - 3,700 mg** Fibrinogen (mean)
INTERCEPT Pathogen Reduced Plasma, Cryoprecipitate Reduced	PCR	Pooled Plasma, Cryo Reduced, Psoralen Treated - 240-295 mL volume

*Fibrinogen content depends on donor plasma fibrinogen levels **Calculated based on pooling of FC10

ISBT / ICCBBA Coding

These are the product codes that correspond to the BloodHub catalog numbers.

Catalog #	Product Code	Description		
INTERCEPT Fibrinogen Complex				
FC10	EA484V00	Apheresis FIBRINOGEN COMPLEX None/XX/<=-18C Cryoprecipitated Psoralen-treated		
	EA489V00	POOLED FIBRINOGEN COMPLEX None/XX/<=-18C Cryoprecipitated Psoralen-treated From 2 donors		
	EA494V00	Thawed Apheresis FIBRINOGEN COMPLEX None/XX/rt Cryoprecipitated Psoralen-treated		
	EA495V00	Thawed POOLED FIBRINOGEN COMPLEX None/XX/rt Cryoprecipitated Psoralen-treated From 2 donors		
FC15	EA485V00	Apheresis POOLED FIBRINOGEN COMPLEX None/XX/<=-18C Cryoprecipitated Psoralen-treated From 2 donors		
	EA490V00	POOLED FIBRINOGEN COMPLEX None/XX/<=-18C Cryoprecipitated Psoralen-treated From 4 donors		
	EA496V00	Thawed POOLED FIBRINOGEN COMPLEX None/XX/rt Cryoprecipitated Psoralen-treated From 4 donors		
	EA500V00	Thawed Apheresis POOLED FIBRINOGEN COMPLEX None/XX/rt Cryoprecipitated Psoralen-treated From 2 donors		
FC20	EA486V00	Apheresis POOLED FIBRINOGEN COMPLEX None/XX/<=-18C Cryoprecipitated Psoralen-treated From 3 donors		
	EA491V00	POOLED FIBRINOGEN COMPLEX None/XX/<=-18C Cryoprecipitated Psoralen-treated From 6 donors		
	EA497V00	Thawed POOLED FIBRINOGEN COMPLEX None/XX/rt Cryoprecipitated Psoralen-treated From 6 donors		
	EA501V00	Thawed Apheresis POOLED FIBRINOGEN COMPLEX None/XX/rt Cryoprecipitated Psoralen-treated From 3 donors		
FC30	EA487V00	Apheresis POOLED FIBRINOGEN COMPLEX None/XX/<=-18C Cryoprecipitated Psoralen-treated From 4 donors		
	EA492V00	POOLED FIBRINOGEN COMPLEX None/XX/<=-18C Cryoprecipitated Psoralen-treated From 8 donors		
	EA498V00	Thawed POOLED FIBRINOGEN COMPLEX None/XX/rt Cryoprecipitated Psoralen-treated From 8 donors		
	EA502V00	Thawed Apheresis POOLED FIBRINOGEN COMPLEX None/XX/rt Cryoprecipitated Psoralen-treated From 4 donors		
FC40	EA488V00	Apheresis POOLED FIBRINOGEN COMPLEX None/XX/<=-18C Cryoprecipitated Psoralen-treated From 5 donors		
	EA493V00	POOLED FIBRINOGEN COMPLEX None/XX/<=-18C Cryoprecipitated Psoralen-treated From 10 donors		
	EA499V00	Thawed POOLED FIBRINOGEN COMPLEX None/XX/rt Cryoprecipitated Psoralen-treated From 10 donors		
	EA503V00	Thawed Apheresis POOLED FIBRINOGEN COMPLEX None/XX/rt Cryoprecipitated Psoralen-treated From 5 donors		

Catalog #	Product Code	Description			
INTERCEPT Pathogen Reduced Plasma, Cryoprecipitate Reduced					
	EA504V00	Apheresis PLASMA ACD-A/XX/<=-18C Cryo reduced Psoralen-treated			
	EA504VA0	Apheresis PLASMA ACD-A/XX/<=-18C Cryo reduced Psoralen-treated			
	EA504VB0	Apheresis PLASMA ACD-A/XX/<=-18C Cryo reduced Psoralen-treated			
	EA505V00	Apheresis PLASMA ACD-A/XX/<=-18C Cryo reduced 1st container Psoralen-treated			
	EA506V00	Apheresis PLASMA ACD-A/XX/<=-18C Cryo reduced 2nd container Psoralen-treated			
	EA516V00	Thawed Apheresis PLASMA ACD-A/XX/refg Cryo reduced Psoralen-treated			
	EA516VA0	Thawed Apheresis PLASMA ACD-A/XX/refg Cryo reduced Psoralen-treated			
	EA516VB0	Thawed Apheresis PLASMA ACD-A/XX/refg Cryo reduced Psoralen-treated			
	EA517V00	Thawed Apheresis PLASMA ACD-A/XX/refg Cryo reduced 1st container Psoralen-treated			
	EA518V00	Thawed Apheresis PLASMA ACD-A/XX/refg Cryo reduced 2nd container Psoralen-treated			
	EA512VB0	POOLED PLASMA CP2D/XX/<=-18C Cryo reduced Psoralen-treated From 2 donors			
PCR	EA510VA0	POOLED PLASMA CPD/XX/<=-18C Cryo reduced Psoralen-treated From 2 donors			
	EA510VB0	POOLED PLASMA CPD/XX/<=-18C Cryo reduced Psoralen-treated From 2 donors			
	EA511VA0	POOLED PLASMA CPDA-1/XX/<=-18C Cryo reduced Psoralen-treated From 2 donors			
	EA511VB0	POOLED PLASMA CPDA-1/XX/<=-18C Cryo reduced Psoralen-treated From 2 donors			
	EA512VA0	POOLED PLASMA CP2D/XX/<=-18C Cryo reduced Psoralen-treated From 2 donors			
	EA512VB0	POOLED PLASMA CP2D/XX/<=-18C Cryo reduced Psoralen-treated From 2 donors			
	EA513VA0	Thawed POOLED PLASMA CPD/XX/refg Cryo reduced Psoralen-treated From 2 donors			
	EA513VB0	Thawed POOLED PLASMA CPD/XX/refg Cryo reduced Psoralen-treated From 2 donors			
	EA514VA0	Thawed POOLED PLASMA CPDA-1/XX/refg Cryo reduced Psoralen-treated From 2 donors			
	EA514VB0	Thawed POOLED PLASMA CPDA-1/XX/refg Cryo reduced Psoralen-treated From 2 donors			
	EA515VA0	Thawed POOLED PLASMA CP2D/XX/refg Cryo reduced Psoralen-treated From 2 donors			
	EA515VB0	Thawed POOLED PLASMA CP2D/XX/refg Cryo reduced Psoralen-treated From 2 donors			

About INTERCEPT Fibrinogen Complex and Pathogen Reduced Plasma, Cryoprecipitate Reduced

Pathogen Reduced Cryoprecipitated Fibrinogen Complex prepared from the INTERCEPT Blood System for Cryoprecipitation ("INTERCEPT Fibrinogen Complex") is indicated for:

- Treatment and control of bleeding, including massive hemorrhage, associated with fibrinogen deficiency.
- Control of bleeding when recombinant and/or specific virally inactivated preparations of factor XIII or von Willebrand factor (vWF) are not available.
- Second-line therapy for von Willebrand disease (vWD).
- Control of uremic bleeding after other treatment modalities have failed.

Limitations of Use

• Pathogen Reduced Cryoprecipitated Fibrinogen Complex should not be used for replacement of factor VIII.

Pathogen Reduced Plasma, Cryoprecipitated Reduced prepared from the INTERCEPT Blood System for Cryoprecipitation is indicated for:

- Transfusion or therapeutic plasma exchange (TPE) in patients with thrombotic thrombocytopenic purpura (TTP).
- Providing coagulation factors, except fibrinogen, factor VIII, factor XIII, and von Willebrand factor (vWF), for transfusion support of patients with appropriate clinical indications.

For questions about these INTERCEPT products, contact Cerus Corporation by phone (855) 835-3523 or visit <u>www.intercept-cryoprecipitation.com</u>.

References

- INTERCEPT Blood System for Cryoprecipitation for the manufacturing of Pathogen Reduced Cryoprecipitated Fibrinogen Complex [Package Insert]. Concord, CA. Cerus Corporation. January 20, 2021.
- INTERCEPT Blood System for Cryoprecipitation for the manufacturing of Pathogen Reduced Plasma, Cryoprecipitate Reduced [Package Insert]. Concord, CA. Cerus Corporation. January 20, 2021.

Contraindications

PATHOGEN REDUCED CRYOPRECIPITATED FIBRINOGEN COMPLEX

- Contraindicated for preparation of blood components intended for patients with a history of hypersensitivity reaction to amotosalen or other psoralens.
- Contraindicated for preparation of blood components intended for neonatal patients treated with phototherapy devices that emit a peak energy wavelength less than 425 nm, or have a lower bound of the emission bandwidth <375 nm, due to the potential for erythema resulting from interaction between ultraviolet light and amotosalen.

PATHOGEN REDUCED PLASMA, CRYOPRECIPITATE REDUCED

- Contraindicated for preparation of blood components intended for patients with a history of hypersensitivity reaction to amotosalen or other psoralens.
- Contraindicated for preparation of blood components intended for neonatal patients treated with phototherapy devices that emit a peak energy wavelength less than 425 nm, or have a lower bound of the emission bandwidth <375 nm, due to the potential for erythema resulting from interaction between ultraviolet light and amotosalen.
- Pathogen Reduced Plasma, Cryoprecipitate Reduced should not be used for replacement of coagulation factors known to be depleted in this product: fibrinogen, factor VIII, vWF and factor XIII.

Warnings and Precautions

PATHOGEN REDUCED CRYOPRECIPITATED FIBRINOGEN COMPLEX

- Only the INTERCEPT Blood System for Cryoprecipitation is approved for use to produce Pathogen Reduced Cryoprecipitated Fibrinogen Complex.
- For management of patients with vWD or factor XIII deficiency, Pathogen Reduced Cryoprecipitated Fibrinogen Complex should not be used if recombinant or specific virally-inactivated factor preparations are available. In emergent situations, if recombinant or specific virally-inactivated factor preparations are not available, Pathogen Reduced Cryoprecipitated Fibrinogen Complex may be administered.

PATHOGEN REDUCED PLASMA, CRYOPRECIPITATE REDUCED

• Only the INTERCEPT[®] Blood System for Cryoprecipitation is approved for use to produce Pathogen Reduced Plasma, Cryoprecipitate Reduced.

Rx only. See package insert for full prescribing information.



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