Commercially Manufactured Plasma Derivative Products

Product Description	Indications	Approx. Vol	Administration	Patient Monitor	Storage
A. ALBUMIN • Ordered according to gm%. • Available from Pharmacy. • 3-5 yrs (shelf life).	• Blood volume expansion. • Replacement of protein.	• 50-250 ml.	• See package insert, formulary, or PDR.	• No hepatitis risk.	• Room temperature.
IMMUNOGLOBLULINS					
A. RH IMMUNE GLOBULIN (RHOGM ^{R}) • Concentrated solution of gamma globulin with anti - Rh_0 (D) activity.	• To prevent formation of anti-D in Rh negative persons who have received Rh positive red blood cells because of: transfusion of platelets or RBC. • Pregnancy a) who have delivered an Rh_0 (D) positive infant, or: b) Infant whose Rh type is unknown or cannot be determined. c) 300 micrograms of Rh globulin given to antepartum patients, - all Rh negative nonsensitize of patients having: 1) genetic amniocentesis 2) diagnostic amniocentesis 3) at 28 weeks of pregnancy 4) with vaginal bleeding	• 300 microgram dose in safety needle syringes.	• Given I.M. within 72 hrs following delivery or invasive procedure or vaginal bleeding or pt receiving Rh positive components.		• Refrigerate.
B. Rhophylac	• Treatment of ITP	• Reconstituted to 2.5 mL of 0.9% Sodium Chloride, Injection. Swirl, do not shake, to dissolve.	• Given IV for the treatment of ITP. May be give IM for the prevention of Rh prophylaxis.	• See product circular.	• Use immediately after reconstitution.
C. **IMMUNE SERUM GLOBULIN (GAMMA GLOBULIN) IM**	• Disease prophylaxis.	• Dosage varies with person's weight.	• See product circular. • I.M.	• See product circular.	
D. IMMUNE GLOBULIN INTRAVENOUS IV (IV GAMMA GLOBULIN, GAMIMUNE, SANDOGLOBULIN) • Available from Pharmacy 50-100 ml single dose vials. • Have an anaphylactic kit available.	• Maintenance treatment of patients unable to produce sufficient amount of IgG antibodies. • May be preferred to that of intramuscular immunoglobulin preparation especially in patients with small muscle mass or with bleeding tendencies in whom I.M. injections are contraindicated. • Congenital agamaglobulinemia immunodeficiency, etc. CONTRAINDICATED in individuals who have had anaphylactic or severe systemic response to Immune Serum Globulin (Human) or have IgA deficiency.	• Usual dose: 100 mg/kg of body weight.	• Administration varies with preparation and manufacturer. See product circular.	• Monitor for signs and symptoms of anaphylactic reactions. • Mild back pain, nausea, flushing have been reported. • If side effects occur, decrease the rate or stop the infusion. • Temperature, BP, P, Resp. baseline and 15 min., then q 15 min. after each rate increase and then q 30 min. during infusion and 30 min. after infusion discontinued.	

Commercially Manufactured Plasma Derivative Products
Factor VIII Products

Product Description	Indications	Approx. Vol	Administration	Patient Monitor	Storage
A. ADVANCED CATEGORY RECOMBINANT F VIII PRODUCTS • Manufactured and formulated without using any human or animal proteins (no forms of blood products used). • Genetically engineered or cloned F VIII which is not derived from animal or human plasma. • Available from Pharmacy. • See package insert, formulary or PDR. • Outdate on bottle.	• Hemophilia A or factor VIII deficiencies. • Prevention and control of hemorrhagic episodes • Perioperative management of patients with hemophilia A	• Varies with manufacturer or lot number.	• Administer within 3 hours of reconstitution. • Gently swirl; do not shake vial • May be given IV push. • As units will vary with lot, give as close to prescribed dose as possible. DO NOT WASTE!! Give entire contents of bottle(s) even if above prescribed dose.	• Risk of viral contamination via human/animal proteins essentially eliminated. • Plasma factor VIII levels • Factor VIII inhibitor levels; if inadequate response to appropriate doses	• Refrigeration recommended.
B. RECOMBINANT FACTOR VIII PRODUCTS 1. Second Generation • Manufacturing process uses human or animal proteins (albumin); however, final formulation has no albumin 2. First Generation • Manufacturing process and final formulation uses human and/or animal proteins. Has albumin in final formulation • Genetically engineered or cloned F VIII which is not derived from animal or human plasma. • Available from Pharmacy. • See package insert, formulary or PDR. • Outdate on bottle.	• Hemophilia A or factor VIII deficiencies. • Prevention and control of hemorrhagic episodes • Perioperative management of patients with hemophilia A	• Varies with manufacturer or lot number.	• Administer within 3 hours of reconstitution. • Gently swirl; do not shake vial • May be given IV push. • As units will vary with lot, give as close to prescribed dose as possible. DO NOT WASTE!! Give entire contents of bottle(s) even if above prescribed dose. .	• Risk of viral contamination via human/animal proteins essentially eliminated. • Plasma factor VIII levels • Factor VIII inhibitor levels; if inadequate response to appropriate doses	• Refrigeration recommended.
C. IMMUNOAFFINITY PURIFIED F VIII PRODUCTS • Pooled products derived from human plasma. • Viral attenuation is augmented by pasteurization or solvent detergent treatment.	• Hemophilia A or factor VIII deficiencies. • Prevention and control of hemorrhagic episodes • Perioperative management of patients with hemophilia A	• Varies with manufacturer or lot number.	• Administer within 3 hours of reconstitution. • Gently swirl; do not shake vial • Draw up with a filtered needle. • May be given IV push. • As units will vary with lot, give as close to prescribed dose as possible. DO NOT WASTE!! Give entire contents of bottle even if it is above prescribed dose.	• Risk of viral contamination via human/animal proteins essentially eliminated. • Plasma factor VIII levels • Factor VIII inhibitor levels; if inadequate response to appropriate doses	• Refrigeration recommended.

Commercially Manufactured Plasma Derivative Products
Factor VIII Products (Continued)

Product Description	Indications	Approx. Vol	Administration	Patient Monitor	Storage
D. INTERMEDIATE OR HIGH PURITY F VIII PRODUCTS DERIVED FROM HUMAN PLASMA • Virally attenuated by heat or solvent detergent treatment. • Humate P is rich in Von Willebrand factor and is recommended for treatment of VWD patients	• Hemophilia A or factor VIII deficiencies. • Prevention and control of hemorrhagic episodes • Perioperative management of patients with hemophilia A • Humate P: Prevention and control of bleeding episodes in patients with hemophilia A or with von Willebrand disease.	• Varies with manufacturer or lot number.	• Administer within 3 hours of reconstitution. • May be given IV push. • Gently swirl; do not shake vial • As units will vary with lot, give as close to prescribed dose as possible. DO NOT WASTE!! Give entire contents of bottle even if it is above prescribed dose.	• Risk of viral contamination very small.	• Refrigeration recommended.
E. PORCINE F VIII • For use in pts. with F VIII inhibitor. • Not derived from human plasma.	• Hemophilia A with inhibitor.	• Varies	• See package insert.	• No risk of transmission of human viruses.	• Refrigeration

Commercially Manufactured Plasma Derivative Products
Factor IX Products

Product Description	Indications	Approx. Vol	Administration	Patient Monitor	Storage
A. RECOMBINANT F IX PRODUCTS • Genetically engineered or cloned F IX which is not derived from animal or human plasma. No human blood components in manufacturing or final formulation. • Available from Rx • *Rixubis™* • *Benefix®*	• Hemophilia B or factor IX deficiencies. • Prevention and control of bleeding episodes in patients with hemophilia B • Perioperative management in adults with hemophilia B	• Varies	• Allow powder and diluent to reach room temperature prior to reconstitution • Administer within 3 hours of reconstitution. • See package insert, formulary, or PDR	• Very small risk of viral transmission.	• Refrigeration recommended.
B. COAGULATION F IX PRODUCTS • Pooled plasma product, virally attenuated. • Much less risk of thrombotic occurrences than with factor IX complex products. • *Alphanine SD* • *Mononine*	• Hemophilia B or factor IX deficiencies. • Prevention and control of bleeding episodes in patients with hemophilia B.	• Varies	• Allow and diluent to reach room temperature prior to reconstitution • Administer within 3 hours of reconstitution. • See package insert.	• Very small risk of viral transmission.	• Refrigeration recommended.
C. F IX COMPLEX CONCENTRATES (PROTHROMBIN COMPLEX CONCENTRATES) • Pooled plasma product, virally attenuated. • Contain factor II, VII & X in addition to factor IX. • Not to be used in patients requiring large or repeated doses due to the risk of thromboembolic complications. • Kcentra™	• Hemophilia B or factor IX deficiencies • Treatment of hemorrhagic episodes	• Varies	• Administer within 4 hours of reconstitution • Discard partially used vials; for single use only • Reconstitute with 20 mL of provided diluent (sterile water for injection, USP) • Record lot number in patient's medical record • See package insert.	• Very small viral risk.	• Room temp until reconstitution

Commercially Manufactured Plasma Derivative Products
Patients with Factor VIII or IX Inhibitors

Product Description	Indications	Approx. Vol	Administration	Patient Monitor	Storage
A. RECOMBINANT F VIIa (ACTIVATED) • Genetically engineered or cloned activated F VII that is not derived from animal or human plasma. No human blood components in manufacturing or final formulation • Available from Rx • Novoseven RT	• Patients with factor VIII or factor IX inhibitors.	• Varies	• Novoseven: Administer within 3 hours of reconstitution. • Inject diluent against side of vial; do not inject diluent directly on powder • Reconstitute ONLY with the histidine diluent provided with NovoSeven • Other products vary; See package insert	• Very low risk of viral transmission.	• Refrigeration recommended. • Outdate on bottle
B. ACTIVATED F IX COMPLEX PRODUCTS • Pooled plasma product, virally attenuated. • Purposely activated so that product contains some F IX, F X, etc. in active form. • To be used in INHIBITOR PATIENTS ONLY. • FEIBA® NF	• Patients with factor VIII or factor IX inhibitors. • Some specific products can be used in deficiencies of factors II, VII or X. Not all products can be used as the amounts of II, VII & X vary from product to product.	• Varies	• FEIBA: Reconstitute with Sterile Water for Injection (warmed to room temperature) using needleless transfer device (both supplied); swirl gently • Administer within 3 hours of reconstitution. • Other products vary; See package insert	• Very low risk of viral transmission.	• Refrigeration recommended.

Product Description	Indications	Approx. Vol	Administration	Patient Monitor	Storage
A. ANTITHROMBIN III • Thrombate III – Pooled plasma product, virally attenuated. • ATryn – Genetically engineered or cloned activated antithrombin that is not derived from animal or human plasma. No human blood components in manufacturing or final formulation. Exposed to goat/goat milk proteins during manufacture.	• Thrombate III – Treatment of hereditary antithrombin deficiency in connection with surgical or obstetrical procedures or when a thromboembolism occurs. • ATryn (Recombinant) – Prevention of post-operative and peri-partum antithrombotic events in patients with hereditary antithrombin deficiency.	• Varies	• Administer within 3 hours after reconstitution • Reconstitute with Sterile Water for injection • Filter the reconstituted product through the sterile filter needle provided • See package insert	• Very low risk of viral transmission.	• Do not refrigerate after reconstitution

Updated 11/2013

Documentation: Lot #(s), expiration date, product name, and # of units infused

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References: Harriet Lane Handbook Peds, , Transfusion & Apheresis Services
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