HEMOPET

CANINE CRYOPRECIPITATE

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California Biologics License #84

1. PRODUCT DESCRIPTION

Canine Cryoprecipitate is a blood product intended for clinical transfusion use in dogs. Blood (about 250 mL) is collected aseptically into 35 mL of citrate-phosphate-dextrose (CPD) anticoagulant-filled blood bags licensed for human use by Baxter Healthcare Corporation.

Hemopet's donor dogs are healthy animals maintained at the Hemopet facility in an isolated, closed colony environment. All donor dogs are of blood type DEA 4(C)and are negative for all other known canine red blood cell antigens, including DEA 1.1 (A1), DEA 1.2 (A2), DEA 7 (Tr), the antigens most associated with clinically significant transfusion incompatabilities in dogs. All product labels indicate the donor's blood type.

All donors receive on-site, 24 hour-a-day veterinary care and maintenance, and have been blood and serologically tested for canine brucellosis, hemobartonellosis, Borrelia burgdorferi (Lyme disease), Dirofilaria immitis (heartworm disease), Ehrlichia canis, Rocky Mountain spotted fever, Coccidioides immitis, Babesia canis, Babesia gibsoni, and plasma levels of von Willebrand factor. All donor dogs are current on immunizations for canine distemper, hepatitis, parainfluenza, leptospirosis, parvovirus, Bordetella, coronavirus and rabies virus.

The expiration date on the label is calculated from the date of collection. Please note this expiration date upon receipt of the blood product at your facility. Blood product that has been delivered and accepted by signature cannot be returned.

Canine Cryoprecipitate is a plasma concentrate prepared from Canine Fresh-Frozen Plasma that has been stored frozen for not more than one year from the date of blood collection. It is prepared after slowly thawing the fresh-frozen plasma at refrigerator temperature and then centrifuging the partially thawed plasma slurry at 4 C. The supernatant plasma is then removed by expressing it into an empty plastic transfer bag which is then labeled and saved. The resultant Canine Cryoprecipitate product is then labeled and refrozen. This product is about 10-fold concentrated over whole starting plasma and has a shelf-life in the frozen state of up to one year.

One "unit" of Canine Cryoprecipitate consists of about 12.5 mL of cryoconcentrated plasma proteins (primarily factor VIII, von Willebrand factor, fibrinogen, fibronectin and a small quantity of other plasma proteins) obtained from the slow thawing of a unit of Canine Fresh-Frozen Plasma at refrigerator temperature, followed by centrifugation of the slurry at 4 C and removal of the majority of supernatant plasma. This product has a shelf-life in the frozen state for up to one year.

2. INDICATIONS

Canine Cryoprecipitate is a plasma concentrate indicated for treatment or pre-surgical prophylaxis of severe bleeding caused by deficiencies of plasma factor VIII (hemophilia A), von Willebrand factor (von Willebrand's syndrome), or fibrinogen. This product is also rich in fibronectin which may be helpful in treating the physiological shock and dehydration associated with severe burns or sepsis.

3. PRECAUTIONS/CONTRAINDICATIONS

A. The volume of cryoprecipitate transfused will depend upon the individual needs of each patient (see 4C).

B. The rate of administration of cryoprecipitate should be slow because the product is a plasma concentrate and may contain gelatinous, proteinaceous material.

C. This product must not be mixed with or administered in the same intravenous or other parenteral line with Lactated Ringer's solution or any other solution containing divalent cations. The safest fluid to mix with or administer via the same infusion apparatus is 0.9% sodium chloride (NaCl).

D. Filters should always be used when administering plasma components/derivatives. Special filter sets that adapt to syringes for filtering smaller volumes of plasma components/derivatives are available for this purpose.

E. Transfusion reactions or blood-transmissible diseases can still arise despite donor blood typing, patient-donor crossmatching and thorough serological screening of donor dogs. Please monitor patient's receiving this product closely for signs of adverse reactions, and refrain from adding medications to the plasma concentrate or into the same infusion system during transfusion. If a reaction occurs, **STOP** the transfusion immediately, and then initiate appropriate supportive measures (see section 5).

F. Gently mix the contents of the plasma bag before administering. Do not use any plasma derivative product if the bag has been damaged and is leaking contents or if the contents are clotted, excessively hemolyzed or discolored.

4. ADMINISTRATION

A. Canine Cryoprecipitate is to be used only in dogs.

B. Canine Cryoprecipitate bags should be carefully removed from the freezer to prevent cracking of the bag as the plastic becomes brittle upon freezing. Thawing should be conducted in a container or bath of warm water with gentle agitation. Do not exceed 37 C/98.6 F as this would coagulate and denature the plasma proteins. Some clinicians have suggested using a microwave to thaw frozen plasma derivatives, but this must be done carefully to avoid creating "hot spots".

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C. The volume of Canine Cryoprecipitate required to control bleeding is calculated by assuming a 10-fold concentration over starting whole plasma and a 50% loss of clotting factor activity during preparation. Therefore the standard dose of whole plasma (about 10 mL/Kg or 4.5 mL/lb) is calculated and then this volume is doubled to determine the number of cryoprecipitate equivalents needed twice daily for the patient, e.g. the patient weighs 30 lbs which equates to a whole plasma volume dosage of 135 mL given twice daily. The equivalent concentrated clotting factor activity in cryoprecipitate comes from 135 x 2 = 270 mL of plasma or 270 : 125 = 2+ units cryoprecipitate (because each unit of cryoprecipitate was prepared from 125 mL of starting plasma). This patient would then receive 2 units of Canine Cryoprecipitate (about 25 mL volume) twice daily.
D. The preferred site for transfusion is intravenous because 100% of the infused material circulates. An alternate site for very young or compromised animals is intraperitoneal although it takes longer to circulate when given by this route.
E. For the recommended rate of administration please refer to section 3B.

5. ADVERSE TRANSFUSION REACTIONS

Complications of transfusion can be manifested by a variety of clinical signs: restlessness, cardiac arrhythmias, irregular respirations, salivation, lip smacking, wretching, vomiting, defecating, urination, edema, erythema, hives, urticaria, fever, jaundice, hemoglobinuria, anuria, DIC, bruising, hemorrhage, acute renal failure and death.

6. SHELF-LIFE AND STORAGE

Canine Cryoprecipitate should be stored frozen preferably at -30 to -70 C but can be kept at normal freezer temperature (-10 to -20 C) upon receipt. It has a shelf-life of up to one year from the date of preparation from Canine Fresh-Frozen Plasma. The expiration date is clearly indicated on the product label.

7. SELECTED REFERENCES

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