HEMOPET

CANINE CRYO-SUPERNATANT PLASMA

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California Biologics License #84

1. PRODUCT DESCRIPTION

Canine Cryo-Supernatant Plasma 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 at your facility. Blood that has been delivered and accepted by signature cannot be returned.

Canine Cryo-Supernatant Plasma is the by-product of producing cryoprecipitates. 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 sealed and labeled as Canine Cryo-Supernatant Plasma.

Canine Cryo-Supernatant Plasma has a shelf-life of up to one year in the frozen state and can be used as a source of certain canine coagulation factors (e.g. the vitamin K-dependent prothombin complex factors II, VII, IX, and X; factors XI, XII, XIII; and fibrinogen), albumin, and globulins. It can then be stored frozen for up to another 4 years for use as a source of canine albumin and globulins.

One "unit" of Canine Cryo-Supernatant Plasma consists of the approximately 112 mL of plasma and 23.5 mL of anticoagulant removed from the unit of cryoconcentrated, centrifuged Canine Cryoprecipitate.

2. INDICATIONS

Canine Cryo-Supernatant Plasma is indicated for treatment or pre-surgical prophylaxis of bleeding caused by deficiencies of all coagulation factors except for factor VIII and von Willebrand factor which has been removed by cryoprecipitation. It also contains nearly the full complement of canine albumin and globulins present in whole plasma which makes it useful for physiological conditions that benefit from plasma protein replacement.

3. PRECAUTIONS/CONTRAINDICATIONS

A. The volume of plasma transfused will depend upon the individual patient's needs which generally should not exceed 3-5 mL/lb of bodyweight given once or twice daily and not more than 10 mL/lb bodyweight over a 24 hour period for normovolemic animals.

B. The rate of administration of plasma should be slow for the first 10-30 minutes to monitor for signs of adverse reaction. The average rate for normovolemic patients should be 10 mL/lb over 4 hours. The rate in hypovolemic patients should not exceed 10 mL/lb/hour. For acute needs, patients can usually tolerate transfusion given at 4-6 mL/minute. For cardiac or other compromised patients at risk for circulatory embarrassment, the rate should be much slower (up to 2mL/lb/hour).

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 blood components. Standard drip type blood administration filters and special filter sets that adapt to syringes for filtering smaller volumes of plasma are available.

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 including circulatory overload, and refrain from adding medications to the plasma bag 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 blood 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 Cryo-Supernatant Plasma is to be used only in dogs.

B. Canine Cryo-Supernatant Plasma 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, but this must be done carefully to avoid creating "hot spots".

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C. The volume of Canine Cryo-Supernatant Plasma needed is usually 10 mL/Kg (4.5 mL/lb) given at a rate not to exceed 4-6 mL/minute twice daily. To control certain bleeding disorders as indicated in section 2, this dosage is given for 3-5 days or until bleeding stops.

To provide a source of plasma proteins for debilitated animals with systemic illnesses and for orphan puppies, plasma is given at 1 mL/oz of neonatal puppy weight up to a maximum of 10 mL, and at 3-5 mL/lb thereafter (for adults use 3-5 mL/lb). Plasma treatment should be repeated daily or at once or twice weekly intervals as needed.

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 Cryo-Supernatant Plasma should be stored frozen at normal freezer temperature (-10 to -20 C) upon receipt. It has a shelf-life of one year as a source of certain coagulation factors (see section 2) and for an additional 4 years as a source of canine albumin and globulins. The expiration date is clearly indicated on the product label.

7. SELECTED REFERENCES

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