



HEMOPET

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CANINE FRESH-FROZEN PLASMA

KEEP FROZEN
California Biologics License #84

1. PRODUCT DESCRIPTION

Canine Fresh-Frozen Plasma is a blood product intended for clinical transfusion use in dogs. Blood is collected aseptically into either a citrate-phosphate-dextrose (CPD) anticoagulant-filled blood bag licensed for human use by Fenwal Blood Technologies or into a citrate-phosphate-dextrose-adenine (CPDA-1) anticoagulant-filled blood bag licensed for human use by Terumo Medical 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 incompatibilities 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*, *Mycoplasma haemocanis* 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 cannot be returned.

Canine Fresh-Frozen Plasma has been processed from freshly collected whole blood in CPD blood bags and frozen within 3 hours of collection. While the expected shelf-life of this product is from 1-3 years, our product has been labeled with a conservative expiration date of 1 year from time of collection. It can be maintained in the frozen state for up to another 4 years (a total of 5 years from time of blood collection) for use as a source of canine albumin and globulins (see section 2).

One "unit" of Canine Fresh-Frozen Plasma consists of approximately 120 mL of plasma and 12 mL of anticoagulant removed within 2 hours of the time of blood collection from a freshly collected and centrifuged unit of Canine Whole Blood (250 mL blood plus 35 mL of CPD or 35 mL of CPDA-1). Smaller units of Canine Fresh-Frozen Plasma consist of either 60 mL of plasma and 4 mL of anticoagulant or 12 mL of plasma and 1 mL of anticoagulant. This product has a shelf-life of 1 year.

2. INDICATIONS

Canine Fresh-Frozen Plasma, after thawing, is indicated for parenteral replacement of coagulation factors, albumin, globulins, electrolytes and other nutrients of plasma. However, in clinically significant hypoalbuminemia secondary to chronic liver, kidney, or gastrointestinal disorders, it is impossible to provide sufficient plasma proteins by giving whole plasma to resuscitate a depleted patient. Canine Fresh-Frozen Plasma can provide plasma volume expansion for resuscitation of hypovolemic patients in shock, but should not be used for routine volume expansion. (Crystalloid or synthetic colloid solutions such as 6 % Hetastarch, Pentastarch or Dextran 70 are preferred). The volume needs of a canine patient for treatment or prophylaxis will depend upon the clinical assessment of the attending clinician or surgeon. This product is most useful in treatment or short term prophylaxis of bleeding and 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 can 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 patients 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 Fresh-Frozen Plasma is to be used only in dogs.

B. Canine Fresh-Frozen 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 30° C / 86° F as this would coagulate and denature the plasma proteins.**

C. The volume of Canine Fresh-Frozen Plasma needed is usually 10 mL/Kg (4.5 mL/lb) given at a rate not to exceed 4-6 mL/minute twice daily. This dosage is given for 3-5 days or until bleeding stops and is used to control serious hemorrhagic coagulopathies (e.g. hemophilia).

To provide a source of plasma proteins for debilitated animals with systemic illnesses and for orphan puppies, plasma is given at 0.25 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, writhing, 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 Fresh-Frozen Plasma should be stored frozen at normal freezer temperature (-10 to -20 C) upon receipt. It has a conservative shelf-life of one year from the date of collection and processing from the donor dog. The expiration date is clearly indicated on the product label. Chest type freezers provide better and more stable storage than standard refrigerator freezers. An indoor/outdoor thermometer can be placed in the freezer to monitor the temperature on a regular basis. Once frozen, plasma bags can be stored in a vertical or horizontal position.

7. SELECTED REFERENCES

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