

CANINE PACKED RED BLOOD CELLS

11561 Salinaz Avenue, Garden Grove, CA 92843 Tel: 714-891-2022

KEEP REFRIGERATED

California Biologics License #84

1. PRODUCT DESCRIPTION

<u>Canine Packed Red Blood Cells</u> is a blood product intended for clinical transfusion use in dogs. Blood (~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, <u>Borrelia burgdorferi</u> (Lyme disease), <u>Dirofilaria immitis</u> (heartworm disease), <u>Ehrlichia canis</u>, Rocky Mountain spotted fever, <u>Coccidioides immitis</u>, <u>Babesia canis</u>, <u>Babesia gibsoni</u>, 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 <u>cannot</u> be returned.

One "unit" of Hemopet <u>Canine Packed Red Blood Cells</u> consists of ~ 125 mL of red blood cells, white blood cells, platelets and a small residual volume of plasma, plus about 10 mL of anticoagulant. This product has been obtained by centrifugation of a 250 mL unit of freshly collected, CPD-anticoagulated canine whole blood, followed by aseptic transfer of the majority of supernatant plasma (~ 125 mL) and about 25 mL of anticoagulant to a plastic transfer bag. About 50 mL of red blood cell nutrient solution (Adsol, saline-dextrose-adenine-mannitol solution, Baxter Healthcare Corporation) is then added to this product to preserve and extend the shelf-life of Canine Packed Red Blood Cells from 28 to 37 days.

2. INDICATIONS

Canine Packed Red Blood Cells are indicated for parenteral replacement of red blood cells to carry oxygen to tissues in order to sustain tissue and cellular viability. This product is essentially equivalent to whole blood in providing this capacity. Packed red blood cells are useful for treating both acute (e.g. traumatic or surgical hemorrhage, acute autoimmune anemia) and chronic (e.g. internal and external parasitism, bone marrow failure, chronic autoimmune anemia) blood loss anemias. The volume of packed red blood cells required to sustain a canine patient will depend upon clinical assessment of the patient's status by the attending surgeon or clinician. The minimum amount needed to stabilize the patient should be given in life-threatening cases of immune-mediated hemolytic disease.

Packed red blood cells are preferred over whole blood for routine use for several reasons. Packed red blood cells stored in nutrient solution have an extended shelf-life of 42 days versus 28 days for whole blood. For cases not requiring replacement of plasma proteins and coagulation factors, packed red blood cells avoid the risk of fluid volume overload for compromised patients and the potential of adverse immunologic reactions to plasma proteins. Red blood cells are also less likely to cause febrile nonhemolytic transfusion reactions. Furthermore, use of red blood cells conserves a source of fresh-frozen plasma for patients needing this product for a variety of other clinical needs (see below).

For surgical procedures, there is <u>no</u> need to transfuse a patient to achieve a PCV within normal limits either before or after surgery because a moderate degree of hemodilution is considered beneficial in most situations.

3. PRECAUTIONS/CONTRAINDICATIONS

- A. While our blood donor dogs are negative for all recognized canine erythrocyte antigens except for DEA 4 (C), it may be advisable to perform a routine major and minor blood <u>crossmatch</u> at 37 C, room temperature and 4 C before transfusing packed red blood cells. Dogs that have received prior blood transfusions should be crossmatched.
- B. The <u>volume</u> of packed red blood cells 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.
- C. The <u>rate</u> of administration of packed red blood cells should be slow for the first 10-30 minutes to monitor for signs of incompatability. 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).
- D. This product <u>must not</u> 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).
- E. <u>Filters</u> should always be used when administering blood cells. Standard drip type blood administration filters and special filter sets that adapt to syringes for filtering smaller volumes of blood cells are available.
- F. <u>Transfusion reactions</u> or <u>blood-transmissible diseases</u> 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 blood 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).
- G. Gently mix the contents of each blood and plasma bag before administering. <u>Do not</u> use any blood product if the bag has been damaged and is leaking contents or if the contents are clotted, excessively hemolyzed or discolored.

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4. ADMINISTRATION

- A. Canine Packed Red Blood Cells are to be used only in dogs.
- B. Use of Canine Packed Red Blood Cells to sustain or resuscitate a patient is usually reserved until the PCV is at or below 15%. As a general rule, the clinician or surgeon may select a "lower limit for alert " of impending transfusion once the PCV reaches 20%.
- C. Refrigerated Canine Packed Red Blood Cells should be warmed to room temperature before transfusion. Do not let this product become overheated (beyond 37 C/98.6 F) as hemolysis will occur.
- D. Whenever Canine Packed Red Blood Cells are to be given, a PCV should be performed before and after the transfusion and again 24 hours later to evaluate the response. The PCV peaks at 24 hours post-transfusion because of the volume contraction that follows transfusional expansion.
- E. The volume of Canine Packed Red Blood Cells needed is calculated as follows:
- i. As a general rule, 10 mL/Kg (4.5 mL/lb) of transfused <u>Packed Red Blood Cells</u> will raise the patient's hemoglobin level by 3 grams or the PCV by 9 points, or
- ii. The volume of donor packed red blood cells needed =
 - (Recipient weight in lbs x 40) x (PCV desired PCV recipient)

PCV of donor packed red blood cells unit '

- * Measure or assume PCV of 70% for packed red blood cells.
- iii. The expected rise in patient PCV =
 - Volume of packed red blood cells transfused x 2

Body weight in lbs

- F. The preferred <u>site</u> for transfusion is intravenous because 100% of the infused material circulates. Alternate sites for very young or compromised animals are intraperitoneal (50% circulates within 24 hours; 70% within 48-72 hours), and intramedullary (80-95% circulates within 5 minutes; trochanteric fossa of the femur is location of choice).
- G. For the recommended rate of administration please refer to Section 3C.

5. ADVERSE TRANSFUSION REACTIONS

<u>Complications of transfusion</u> 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. Delayed hemolytic reactions can occur days to weeks following transfusion and the animal may become anemic and hemoglobinuric. The direct Coombs test is positive in these patients.

6. SHELF-LIFE AND STORAGE

<u>Canine Packed Red Blood Cells</u> stored in nutrient solution have a shelf-life of 37 days from the date of collection from the donor dog. Units should be stored at normal refrigerator temperature (1 to 6 C) upon receipt. The expiration date is clearly indicated on the product label. Blood bags should be stored in a vertical position with an airspace left to provide breathing room between bags.

7. SELECTED REFERENCES

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Tel: (714) 891-2022 Fax: (714) 891-2123