PACKAGE INSERT - CANINE WHOLE BLOOD AND PACKED RED BLOOD CELLS

NOTICE TO ALL USERS

The package insert is considered an extension of the blood and component container labels as the space on those labels is very limited.

No MSDS is required for these products.

This package insert is supplied to conform with applicable government regulations. This document should be kept on file and readily available to personnel using this product.

Blood and blood components are biologic products and, in the form of cellular products, living canine tissue intended for use in the treatment of canine patients. Professional judgment based on clinical evaluations determines the selection of components, dosage, the rate of administration and decisions in situations not covered in this general statement.

WARNING. Despite serological testing, the risk of transmitting infectious agents to the patient is present. Careful donor selection, care, and available laboratory tests do not eliminate the hazard. Also, septic, and toxic reactions can result from transfusion of bacterially contaminated blood and components. Such reactions are rare, but may be life threatening. In addition, blood components may contain certain immunizing substances other than those indicated on the label. Therefore, this package insert as a whole or in part cannot be considered or interpreted as an expressed or implied warranty of the safety or fitness of the described blood or blood component when used for their intended purpose. Use of specific blood components as indicated by the individual patients clinical condition is needed to prevent inappropriate transfusion. Please note that whole blood is rarely considered first choice for transfusion.

Autologous transfusion techniques (such as intraoperative salvage and presurgical donation) should be considered whenever feasible, to reduce the risks of disease transmission and immune reactions from homologous donations.

GENERAL INFORMATION

DONORS

Blood and components described in this package insert have been collected from canines in a closely monitored donor community. The blood type of each donor is indicated on the product label. The donors receive on site health care, and all animals are current on immunizations to include: Canine Distemper, Adenovirus type 2, Leptospirosis, Parainfluenza, Canine Parvo Virus, and Rabies.

Testing of Donor Blood

Testing of the donor's blood is required before admittance into the community as a donor and annually thereafter. All donors must test serologically or PCR negative for a variety of canine infectious diseases. For a complete list of diseases tested for, please visit www.**ABRINT**.net.

The label on the container indicates donor's bloodtype: DEA 1 negative, DEA 1, DEA 5, DEA 7 negative, DEA 1 positive, or DEA 4 only.

BLOOD AND COMPONENT LABELING

Labels contain the following information:

1. The name of the blood product.
2. Proper temperature range for storage.
3. Minimum weight or volume.
4. Company name, address, telephone number and California Biologics registration number (if applicable).
5. Expiration date of the blood component.
6. Donor (serial) identification number.
7. Blood type of the donor.
8. Statement regarding this package insert.

GENERAL INSTRUCTIONS FOR WHOLE BLOOD (WB) AND ALL COMPONENTS

The following general instructions pertain to WB and all the components described in this package insert.

- The intended recipient must be properly identified before the transfusion is started.
- The plastic blood container must not be vented.
- Blood and blood components must be administered through an appropriate blood filter. A variety of commercially available blood filters are available to suit specific volume requirements. A blood administration set with standard (170-260 µl) clot filter is recommended when administering volumes greater than 50 mL. An 18-µl blood filter (HEMO-NATE® blood filter) is recommended for volumes less than 50 mL. Syringe filters not specifically produced and approved for blood should never be used for any product containing red cells.
- Before use, bags of blood or components should be gently agitated to thoroughly mix contents.
- No medications or solutions may be added to or infused through the same tubing with blood or components except 0.9% Sodium Chloride, Injection (USP).
- Lactated Ringer's, Injection (USP) or other electrolyte solutions containing calcium should **NEVER** be added to or administered concurrently with blood or components collected in an anticoagulant containing citrate. All products described below contain and are collected into anticoagulants which contain citrate.
- Blood and components should be visually inspected for significant changes in color and viscosity. If upon visual inspection the fitness of a component is questioned, call Animal Blood Resources at (800) 243-5759 for further evaluation. A slight pink tinge to the supernatant due to some free hemoglobin may be present and is acceptable for transfusion.
- Blood and components may be warmed to no more than 37° C during transfusion, if warming is clinically indicated.
- Blood components have been prepared by techniques that aid in preserving sterility up to the time of expiration. If the container is entered in a fashion that could contaminate the contents of the container for any reason the component expires 4 hours after entry if maintained at room temperature (20° - 24° C), or 24 hours after entry if refrigerated (1° - 6° C).
- Unless otherwise indicated by the patient's clinical condition, the rate should be slow, no greater than 0.11 mL / pound of body weight for the first 30 minutes of the transfusion. The patient should be observed during this period since some life-threatening reactions occur after the infusion of only a small volume of incompatible blood. If a transfusion reaction occurs, the transfusion should be discontinued immediately, and appropriate therapy initiated. The infusion should not be restarted.
- Completion of the transfusion should be prior to component expiration or within 4 hours of warming to room temperature, whichever is sooner
- A crossmatch is highly suggested before every transfusion. Blood transfusions should never be considered safe, even under optimum conditions, and should not be given unless there is no other acceptable treatment.
- The blood type of both the donor and the recipient should be known before transfusing whenever possible. When the blood type of the recipient is not known, only blood from type DEA 1 NEGATIVE donors should be given. First time transfusions with donors and recipients of unknown blood types should **NEVER** be considered safe.

SPECIFIC INSTRUCTIONS FOR WB AND RED BLOOD CELLS (RBCs)

WHOLE BLOOD

Description

WB contains the RBCs and plasma components of blood. Platelets and white blood cells in stored blood are nonviable. A 125 mL (single) unit of WB with anticoagulant has a volume of approximately 125 mL ± 10% with a packed cell volume (PCV) of 35 - 50% ±. This assumes a donor PCV of 40 - 55% ±. Whole blood also comes in 250 mL (double) unit of approximately 250 mL ± 10% and 500 mL (quad) units of approximately 500 mL ± 10%. The volume of whole blood (± 10%) can be found on the label.

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Anticoagulant	Exp. Date (from day of draw)
Citrate Phosphate Dextrose Solution, USP (CPD)	28 days
Citrate Phosphate Dextrose Adenine Solution (CPDA-1)	35 days
Citrate Phosphate Double Dextrose Solution (CP2D)	28 days

All WB, Canine is collected in CPDA-1 unless otherwise stated.

Actions

WB provides RBCs to carry oxygen to tissues. It also is a volume expander and a source of proteins with oncotic and certain non-labile coagulation properties.

Indications

WB is indicated only for those patients who have a symptomatic deficit in oxygen carrying capacity combined with hypovolemia of sufficient degree to be associated with shock. If only the former is present, the component of choice is RBCs. Whole blood cannot be considered a source of viable platelets, white cells or of therapeutic levels of labile coagulation Factors V and Vlll.

Contraindications

Depending upon the condition of the patient, transfusions containing red cells may not be necessary even with low hemoglobin concentration. Do not use WB or other RBC components if anemia can be treated with specific medications, and if the clinical condition of the patient permits sufficient time for these agents to promote erythropoiesis.

Do not use WB when blood volume can be safely and adequately replaced with other volume expanders such as 0.9% Sodium Chloride, Injection (USP) or Lactated Ringer's, Injection (USP).

Do not use WB to correct coagulation deficiencies when they can be better treated by appropriate components.

For a complete list of side effects and causes related to canine transfusions, please visit www.**ABRINT**.net.

Dosage and Administration

WB should not be used unless donor and recipient are of the same blood type, the recipient is blood typed and known to be DEA 1 positive, or the donor has been blood typed and is known to be DEA 1 negative. Crossmatching should be done even when donor and recipient have been blood typed and are known to be of the same blood type. The above criteria should always be met unless withholding blood might result in loss of life. The volume of a transfusion depends on the clinical situation. One mL of whole blood contains enough RBCs to raise the PCV approximately one percentage point per kilogram of body weight.

The rate of transfusion after an initial slow drip (0.11 mL per pound of body weight over a 30-minute period) should be as fast as tolerated. In an animal with a normal state of hydration, whole blood may be infused at a rate of 10 mL per pound of body weight per 24-hour period. This rate may be significantly increased in hypovolemic patients. Due to the wide range of infusion rates, close monitoring of the patient is essential to determine the rate which is appropriate for that individual, and this rate may need to be adjusted accordingly throughout the transfusion. If the patient requires a slow transfusion rate, then consideration should be given to the transfusion of RBCs rather than WB.

RBCs

Description

The component RBCs are prepared by centrifugal or gravitational separation of the red cells from plasma. RBCs are collected in CPD or CP2D, and stored on additive solution (AS) to extend shelf life. A unit of RBCs on AS-3 solution has a PCV of 60 - 75% ±. This assumes a donor PCV of 40 - 55% ±. A single unit contains minimum 100 mL+ of RBCs in addition to 50 mL of AS, a double unit contains minimum 200 mL+ of RBCs in addition to 100mL of AS. This extra fluid volume should not be included when determining the volume of RBCs needed for transfusion, but must be considered as part of the patient's total fluid requirement. Some platelets and or white blood cells may have been removed during processing and are nonviable due to refrigerated storage.

AS consist of glucose, adenine, and sodium chloride in water for injection (USP). Additive solution formula one (AS-1), additive solution formula five (AS-5) and SAG-M also contain mannitol as a red blood cell stabilizing agent. Adenine-Saline formula three (AS-3) contains additional citrate and phosphate, and does not contain mannitol. All ABRI canine RBCs are preserved using SAG-M.

RBCs components may be prepared from WB collected in CPDA-1, CPD or CP2D, but unless otherwise noted, ABRI red cells are collected in CPD or CP2D. RBCs which are not suspended on AS solution have the same shelf life as the whole blood from which they are removed, see above. RBCs suspended on AS have a shelf life of 42 days, and are so identified on the label. The expiration date is indicated on the label.

Actions

This component increases the oxygen carrying capacity of the recipient's blood by increasing the circulating red blood cell mass.

Indications

RBCs are the component of choice for virtually all patients with a symptomatic deficit of oxygen carrying capacity. This component may be used to help restore blood volume following significant hypovolemia without significant red cell mass deficit.

Contraindications

Do not use RBCs when anemia can be corrected with specific medications. See 'Whole Blood, Contraindications.'

Side Effects and Hazards

Side effects and hazards of RBCs (including disease transmission, bacteremia or endotoxemia, and hemolytic transfusion reactions) are similar to those for WB. However, the incidence of allergic reactions, circulatory overload and metabolic complications is lower because removing plasma reduces volume and the quantity of metabolites and antibodies. The risk of disease transmission remains the same. If AS solution containing mannitol is used, RBCs contain 0.375 g of mannitol per Double (300 mL) unit. The amount of mannitol in approved additive solutions is far below that used to achieve a diuretic effect. It is unlikely that any side effects of the mannitol would be observed.

Dosage and Administration

The dosage and administration of RBCs are similar to those for WB. Due to the addition of AS solution to the red cells, additional dilution with 0.9% Sodium Chloride, Injection (USP) to improve flow is not needed. Do not add lactated ringers or any other fluids.

REFERENCES

A reference list is available upon request from Animal Blood Resources International.

Animal Blood Resources International
PO Box 609
Stockbridge, MI 49285

(800) 243-5759

(707) 678-7350 **PST** and International

(517) 851-8244 **EST** and International

customerservice@abrint.net

www.abrint.net

pRBC and WB Formulary

Packed Red Blood Cells

Dose 1 ml/kg for each 1% desired increase in PCV.

Rate Initially 5 ml/kg/hr. Max rate 10 - 20 ml/kg over 6 hours.

Whole Blood

Dose 2 ml/kg for each 1% desired increase in PCV.

Rate Initially 5 ml/kg/hr. Max rate 10 - 20 ml/kg over 6 hours.