PACKAGE INSERT - CANINE FRESH FROZEN AND FROZEN PLASMA

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 canine donors in a closely monitored donor community. The blood type of each donor is indicated on the product label. The colonies 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 colony as a donor and annually thereafter. All colony 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.

PLASMA COMPONENTS

FRESH FROZEN PLASMA

Description

Fresh Frozen Plasma (FFP) is separated and frozen within eight hours of collection of whole blood. A unit of FFP contains the labile plasma coagulation Factors V and Vlll (including vWf). Platelets, if present, are not viable. FFP comes in three sizes: a mini unit which contains 60 - 90± mL, a standard unit which contains approximately 120 - 145 mL ±, and a double unit which contains approximately 240 - 265 mL ±. These ranges are due to differences in donor PCV's.

Actions

FFP contains plasma proteins including all coagulation factors both labile and non-

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labile.

Indications

FFP is indicated for use in control of bleeding in patients who require replacement of labile plasma coagulation Factors (V and VIII including vWf) when simultaneous blood volume expansion is required. When blood volume expansion is not required, Lyophilized Cryoprecipitate may be used. FFP may also be used in cases where Frozen Plasma (FP) is indicated. FFP is indicated for patients with thrombotic thrombocytopenic purpura (TTP) when platelet inactivation is due to an absence of vWF. FFP does not contain platelets.

Contraindications

Do not use FFP when coagulopathy can be corrected more effectively with specific therapy, such as Lyophilized Cryoprecipitate, vitamin K, etc. Do not use FFP 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).

NOTE: Lyophilized Cryoprecipitate not available in the state of California.

Side Effects and Hazards

As described for Whole Blood (WB), side effects and hazards may include febrile, hemolytic and allergic reactions; circulatory overload; and transmission of infectious diseases. If massive volumes of plasma are used, citrate toxicity, hypothermia and other metabolic problems may occur.

Antibodies in the plasma may react with the recipient's red cells, causing a positive direct antiglobulin test, possibly hemolysis and, rarely, noncardiogenic pulmonary edema.

Dosage and Administration

A crossmatch should always be performed before plasma is administered. Plasma should be DEA 1 compatible with the recipient's red cells, from DEA 1 negative donors or produced in a manner that insures no red cell contamination. Plasma produced from whole blood collection cannot be guaranteed free of red cells. Unless labeled otherwise, all ABRI plasma comes from DEA 1 negative donors. The volume transfused depends on the clinical situations and patient size. Some literature recommends two mL to five mL per pound of body weight up to 20 mL per pound of body weight. Dosage should be guided by close patient monitoring. Do not use the plasma if there is evidence of container breakage or of thawing during storage. Plasma may be thawed at a temperature between 30° and 37° C using gentle agitation. Use a watertight protective plastic overwrap (such as a ziplock bag) if a waterbath is used. Microwaves are not recommended for thawing plasma. FFP thawed in a refrigerator may be refrozen, but should be relabeled as frozen plasma. Plasma thawed and refrozen in this way has an expiration date of five years from the date of collection.

FROZEN PLASMA

Description

Frozen Plasma (FP) consists of the anticoagulated clear portion of blood that is separated by centrifugation or sedimentation no later than five days after the expiration date of the WB. FP may be stored refrigerated for up to five days after the expiration date of the whole blood from which it is removed. This freeze by date is indicated on the plasma carton. FP comes in three sizes: a mini unit which contains 50 - 90+ mL, a standard unit which contains approximately 120 - 145 mL ±, and a double unit which contains approximately 240 - 265 mL ±. These ranges are due to differences in donor PCV's. All non labile coagulation factors are present. Plasma components for transfusion may be prepared from WB collected in all approved anticoagulant solutions except Heparin solution.

Actions

FP contain plasma proteins, including nonlabile clotting factors such as fibrinogen, Factor VII and Factor IX. FP does not contain the labile clotting Factors V, VIII and vWF. FP does not contain platelets.

Indications

These components are indicated for the treatment of non labile clotting factor deficiencies, such as Warfarin poisoning, and plasma protein deficiencies. ***Note: Plasma is not the first treatment of choice for protein replacement or volume expansion. See contraindications.***

Contraindications

Do not use FP when coagulopathy can be corrected more effectively with specific therapy, such as vitamin K. Do not use FP for replacement of labile coagulation factors such as Factors V and Vlll, including von Willebrand factor (vWf). Do not use these components 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).

Side Effects and Hazards

The side effects and hazards of FP are similar to those for FFP.

Dosage and Administration

The dosage and administration of FP are the same as for FFP. FP should be used as soon as possible but no more than 24 hours after thawing (stored at 1° - 6° C) when administered as a source of labile coagulation factors. Frozen plasma thawed in a refrigerator may be refrozen.

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

customerservice@abrint.net

www.abrint.net

FFP and FP Formulary

Dose	6 - 15 ml/kg for coagulopathy. 30 - 45 ml/kg for hypoalbuminemia.
Rate	Max rate 6 - 20 ml / kg / hour with goal of 6 hour administration.