

# Summary Chart of Blood Components

Component	Major Indications	Action	Not Indicated For	Special Hazards	Rate of Infusion
Whole Blood	Symptomatic anemia with large volume deficit	Restoration of oxygen carrying capacity, restoration of blood volume	Condition responsive to specific component. Labile coagulation factors, deteriorate within 24 hour after collection. Platelets and white cells are not viable in stored blood	Infectious diseases: septic, toxic, allergic, febrile reactions; circulatory overload	For massive loss, fast as patient can tolerate, but less than four hours per unit
Red Blood Cells	Symptomatic anemia	Restoration of oxygen carrying capacity	Pharmacologically treatable anemia, Coagulation deficiency	Infectious diseases: septic, toxic, allergic, febrile reactions; circulatory overload	As patient can tolerate but less than 4 hours per unit
Fresh Frozen Plasma		Source of labile and non labile plasma factors	Condition responsive to volume replacement	Infectious diseases, circulatory overload	Less than 4 hours per unit
Frozen Plasma		Source of non labile coagulation factors	Deficit of labile coagulation factors or volume replacement	Infectious diseases, circulatory overload	Less than 4 hours per unit

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## PACKAGE INSERT - CANINE WHOLE BLOOD AND BLOOD COMPONENTS



### 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 involved in the use of 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:** In spite of 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. For example, plasma may contain red blood cells and platelets as well as plasma. 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 an appropriate choice for transfusion. See the section Whole Blood - Indications, below.

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

**GENERAL INFORMATION**

**DONORS**

Blood components described in this Package Insert are collected from canine donors which are maintained in isolated, controlled access colonies. 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.

Blood from donors maintained in controlled access colonies generally carries a lower risk of disease transmission than blood from volunteer donors.

### Testing of Donor Blood

Testing of the donor's blood is required before an animal is admitted into the colony as a donor and annually thereafter. All colony donors must test serologically or PCR negative for Canine brucellosis, Ehrlichia canis, Borrelia burgdorferi, Babesia, Anaplasmosis, Rickettsia rickettsia, Hepatozoon, Neirocristis, Bartonella, hemotropic Mycoplasmas, Leishmania, and

Dirofilaria immitis. The label on the container indicates whether the donor is DEA 1 negative, DEA 1 positive, or DEA 4 only.

**BLOOD AND COMPONENT LABELING**

Labels contain the following information:

- The Name of the Blood Product.
- Proper Temperature range for storage.
- The minimum weight or volume.
- Company name, address, telephone number and California Biologics registration number (if applicable).
- The expiration date of the blood component.
- The donor (serial) identification number.
- Blood type of the donor.
- Statement regarding this Package Insert.

### GENERAL INSTRUCTIONS FOR WHOLE BLOOD AND ALL COMPONENTS

The following general instructions pertain to Whole Blood 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 may be administered through any appropriate blood filter. A blood administration set with standard (170-260 µ) clot filter is recommended when administering volumes greater than 50 mL. An 18 micron blood filter (HEMO-NATE<sup>®</sup> 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 of the products described below contain and are collected into anticoagulants which contain citrate.
- Hemolysis may become evident during the storage of components containing red blood cells. Blood and components should be inspected for bacterial growth. If upon visual inspection the fitness of a component is questioned because of, for example, presence of hemolysis, a significant color change in the contents of the blood bag as compared to the tubing segments, floccular material, cloudy appearance or other problems, the component should not be used. Call Animal Blood Resources at 1-800-243-5759 for further evaluation. A slight pink tinge to the supernatant due to some free hemoglobin may be present and acceptable for transfusion.

- When the frozen products in a vessel both, care must be taken to prevent contamination of entry ports. The use of watertight protective plastic over wraps (such as ziplock bags) is recommended.
- Blood and components may be warmed to no more than 37° C during transfusion, if warming is clinically indicated for situations such as hypothermia, blood exchange or massive transfusions.
- 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. If blood or components cannot be infused in 4 hours, they should be divided into aliquots before reaching 6 degrees C and stored appropriately in the refrigerator until needed.
- A crossmatch should be conducted before every transfusion.
- 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 N (DEA1VE) donors should be given. First time transfusions without **NEVER** be considered safe. Blood recipients should be closely observed safe, even under optimum conditions, and should not be given unless there is no other acceptable treatment.

### SPECIFIC INSTRUCTIONS FOR WHOLE BLOOD AND COMPONENTS

**WHOLE BLOOD**

**Description**

Whole Blood contains the red blood cells and plasma components of blood. Platelets and white blood cells in stored blood are nonviable. A 125 mL (single) Unit of Whole Blood with anticoagulant has a volume of approximately 125 mL ± 10% with 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 (within 10% can be found on the label. Currently used anticoagulant solutions for the collection of Whole Blood include the anticoagulants Citrate Phosphate Dextrose Adenine Solution (CPDA-1); and Citrate Phosphate Double Dextrose Solution (CP2D).

The refrigerated shelf life of the Whole Blood is determined by the type of anticoagulant used: CPDA-1 provides a shelf life of 35 days, CPD and CP2D give a shelf life of 28 days. This expiration date is indicated on the product label. Product Whole Blood, Canine is collected in CPDA-1 unless otherwise stated.

**Actions**

Whole Blood provides red blood cells to carry oxygen to tissues. It also is a blood volume expander and a source of proteins with oncotic and plasma non labile coagulation properties.

**Indications**

Whole Blood 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 Red Blood Cells. Whole Blood cannot be considered a source of viable platelets, white cells or of therapeutic levels of labile coagulation Factors V and VIII.

**Contraindications**

Depending upon the condition of the patient, transfusions containing red cells may not be necessary even with low hemoglobin concentration. Do not use Whole Blood or other red blood cell components if anemia can be treated with specific medications such as iron, vitamin B12, or folic acid.

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## CANINE WHOLE BLOOD AND BLOOD COMPONENTS

acid, and if the clinical condition of the patient permits sufficient time for these agents to promote erythropoiesis.

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

**Side Effects and Hazards**  
The principal side effects and hazards of Whole Blood are:

Hemolytic transfusion reactions usually occur when donor red blood cells and recipient plasma are incompatible. Undetected serologic incompatibilities can cause transfusion reactions, but most immediate reactions occur when there is a DEA-1 incompatibility. To reduce the risk of transfusion reactions a major and minor crossmatch should be conducted before every transfusion, including first transfusions. This is true even if the patient has been crossmatched to a repeat donor of the same type.

The following severe transfusion reactions are characterized by shock, fever, dyspnea, auricular character, hypotension, erratic respiration, salivation, cardiac arrhythmias, erratic respiration, salivation, hemoglobinuria, edema, disseminated intravascular coagulation (DIC), abnormal bleeding, vomiting and urticaria. These reactions may result in death in anesthetized patients, hypotension and evidence of DIC may be the first indications of a transfusion reaction. Hemoglobinemia, hemoglobinuria are usually detectable. Renal failure may ensue. The transfusion must be stopped. Treatment includes management of shock and the judicious administration of fluids and diuretics.

Delayed hemolytic reactions may also occur, usually in patients with antibodies undetectable at the time of transfusion. This type of reaction may mimic autoimmune hemolytic anemia with a positive direct antiglobulin test. The signs may include fever, hemoglobinuria, hyperbilirubinemia, and/or a progressive unexplained fall in hemoglobin 4 - 14 days after transfusion or continued anemia despite transfusion therapy. The usual course of delayed reactions is benign and requires no treatment. Rarely, delayed transfusion reactions may be severe and fatal.

Some uncommon causes of acute non-immunologically mediated hemolysis that occur in patients include:

- administration of a hypotonic fluid or contamination of the donor blood
- acute hemolytic anemia from, such as overheating or freezing.
- improper handling of the blood, such as being stored in a non-sterile container.
- transfusion of incompatible blood. When hemolytic levels are high, the patient's course is usually benign, although hemoglobinuria, chills, DIC, renal failure, and fever may occur.

Treatment for the infrequent severe reaction are the same as those for an immediate hemolytic transfusion reaction.

Transfusion of infectious disease may occur in spite of careful donor selection and testing. Bacterial contamination of blood and components is rare. However, the presence of gram-negative bacilli can cause severe endotoxin reactions, including shock, and rarely, death. When a blood recipient experiences chills, high fever or hypotension during or immediately after the transfusion, the possibility that the transfused product may have been bacterially contaminated should be considered. Septic and toxic reactions may be life threatening, and management must

have severe liver or kidney disease. Following are examples of metabolic complications:

- Hypothermia with the risk of cardiac arrhythmia may occur in rapid, massive transfusion with cold blood or when cold blood is administered through a central venous pressure line. Hypothermia may complicate other metabolic changes and offset oxygen release from hemoglobin. Warming the blood during its passage through the transfusion set to no more than 37°C can prevent this complication.
- Citrate toxicity due to complexing of ionized calcium by the anticoagulant in the blood is very rare. The calcium stores of the body are large, and citrate anticoagulant is usually rapidly metabolized.

Symptoms can range from muscle tremors to cardiac arrhythmia, and even cardiac arrest. In the absence of underlying pathology, contributing to hypocalcemia, most citrate reactions require no treatment other than slowing or discontinuing the transfusion.

c. Acidosis, which may occur initially during massive transfusion, rarely requires treatment. The citric acid is rapidly converted to pyruvate and lactate. With subsequent metabolic alkalosis, Whole Blood should be used unless donor and recipient are of the same blood type, the 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 Red Blood Cells to raise the PCV approximately 1 percentage point per pound of body weight.

The rate of transfusion after an initial slow drip (0.1 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 Red Blood Cells rather than Whole Blood.

**Components of Whole Blood are described below.**

**RED BLOOD CELLS**  
Description  
The component Red Blood Cells is prepared by centrifuging granular plasma from collected cells from the Red Blood Cells and plasma in CPD or CP2D and stored on Adenine-Saline Solution to extend shelf life. A unit of Red Blood Cells 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 Red Blood Cells in addition to 20 mL ± of AS, a Double Unit contains minimum 200 mL ± of Red Blood Cells in addition to 100 mL ± of AS. **This extra fluid volume should not be included when determining the volume of RBCs needed for transfusion, but total fluid requirement. Some platelets and/or white blood cells may have been removed during processing and are non-viable due to refrigerated storage.**

AS-3 solutions consist of glucose, adenine and sodium chloride in water for injection (USP).

Additive Solutions formula one (AS-1) and five (AS-5) 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.

Red Blood Cell components may be prepared from Whole Blood 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-3 solution have the same shelf life as the whole blood from which they are removed. CPDA-1 provides 35 days, CPD and CP2D provides 21 days. Red Blood Cells suspended on Adenine-Saline solution 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 quantity of red blood cell mass.

**Indications**  
Red Blood Cells is the component of choice for virtually all patients with a symptomatic deficit of oxygen carrying capacity. The component may be used to replace red blood cells in patients with significant hypovolemia without significant red cell mass deficit.

**Contraindications**  
Do not use Red Blood Cells when anemia can be corrected with specific medications. See "Whole Blood, Contraindications."

**Side Effects and Hazards of Red Blood Cells**  
(including disease transmission, bacteremia or endotoxemia, and hemolytic transfusion reactions) are similar to those for Whole Blood. 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-3 solution containing mannitol is used, Red Blood Cells contain 0.375g 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. Mannitol currently is not present in ABRI Red Cells.

**Dosage and Administration**  
The dosage and administration of Red Blood Cells are similar to those for Whole Blood. (See "Whole Blood, Side Effects and Hazards, Circulatory Overload Reactions.") Due to the addition of 0.9% Sodium Chloride Injection (USP) to improve flow is not needed. Do not add lactated ringers or any other fluids.

**PLASMA COMPONENTS**  
**FRESH FROZEN PLASMA**

Fresh Frozen Plasma (FFP) is separated and frozen within 8 hours of collection of whole blood. A Unit of Fresh Frozen Plasma Contains V and VII (including vWF, Platelets, if present, are not included). A single unit contains approximately 120 mL to 145 mL ± of Fresh Frozen Plasma. A double unit contains approximately 240 - 265 mL ± of Fresh Frozen Plasma. A mini unit contains approximately 60 mL to 90 mL ± of Fresh Frozen Plasma. These ranges are due to differences in donor PCV's.

**Actions**  
FFP contains plasma proteins including all coagulation factors both labile and non-labile. **Indications**  
Fresh Frozen Plasma 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 is indicated. FFP is indicated for patients with thrombotic thrombocytopenic purpura (TTP) when platelet inactivation is due to an absence of vWF. **Fresh Frozen Plasma 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, 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 a DEA-1 negative donor 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 2 mL to 5 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.

Fresh Frozen plasma thawed in a refrigerator may be frozen and should be relabeled with the date. Plasma thawed in a waterbath should have an expiration date of five years from the date of collection.

**DESCRIPTION**  
FROZEN PLASMA

Frozen Plasma consists of the anticoagulated clear portion of blood that is separated by centrifugation or sedimentation no later than 5 days after the expiration date of the Whole Blood. Frozen Plasma may be stored refrigerated for up to 5 days after the expiration date of the whole blood from which it is removed. This freeze by date is indicated on the plasma carton. Frozen Plasma comes in three sizes: a mini unit which contains 50 - 90 mL of Frozen Plasma, a standard unit which contains approximately 120 - 145 mL ± of Frozen Plasma and a double unit which contains approximately 240 - 265 mL ± of Frozen Plasma. 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 Whole Blood collected in all approved anticoagulant solutions except Heparin Solution.

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

**Indications**  
These components are indicated for the treatment of non-bleeding 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 Frozen Plasma when coagulopathy can be corrected more effectively with specific therapy, such as vitamin K.

Do not use Frozen Plasma for replacement of labile coagulation factors such as Factor V, and VIII. Do not use Whole Blood, Whole Blood with Volume Expanders (WVE), or FFP. 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 FFP are similar to those for Frozen Plasma.

**Dosage and Administration**  
The dosage and administration of FFP are the same as for Fresh Frozen Plasma. FFP 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.

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