Summary Chart of Blood Components

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

PACKAGE INSERT - FELINE WHOLE BLOOD AND BLOOD COMPONENTS

NOTICE TO ALL USERS

The Package Insert is a supplement to 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 inform the user of the product use and conform with applicable government regulations. This document should be kept on file and readily available to personnel involved in the use of these products.

Blood and blood components are biologic products and, in the form of cellular products, living feline tissue intended for use in feline patients at the discretion of the attending veterinarian. 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. This is especially true regarding feline viruses that do not currently have highly successful diagnostic tests and vaccination agents available. 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 patient's clinical condition is needed to prevent inappropriate transfusion.

Autologous transfusion techniques (such as intraoperative salvage and pre-surgical donation) should be considered whenever feasible in the perioperative setting, 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 feline 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 Rabies, Rhinotracheitis, Calici and Panleukopenia. Blood from donors maintained in controlled access colonies generally carries a lower risk of disease transmission than blood from volunteer donors. These risks for feline infectious agents cannot be eliminated under the current state of the art and it must be considered that a risk of disease transmission may be present.

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 negative for FeLV, FIV and are screened for Haemobartonella felis. The label on the container indicates whether the donor is feline blood type A, type B or type AB.

BLOOD AND COMPONENT LABELING

Labels contain the following information:

1. The name of the product.
2. The temperature range in which the component is to be stored.
3. The contents or volume (standard contents, i.e., as prepared according to this Package Insert, is assumed unless otherwise indicated on the label or in Package Insert supplements).
4. ABRI's name, address, telephone number.
5. California Biologics registration number, if applicable.
6. The expiration date of the blood component.
7. The donor (serial) identification number.
8. Blood type of the donor
9. 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 must be administered through an appropriate blood filter. A blood administration set with standard (170-260 µ) clot filter is recommended when administering volumes greater than 50 mL. An ABRI Feline Administration set or 18 micron blood filter (HEMO-NATE® blood filter or equivalent) is recommended for volumes less than 50 mL.
- Before use, bags of blood or components should be gently rocked 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 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. A slight pink tinge to the supernatant due to some free hemoglobin may be present and is acceptable for transfusion. Call Animal Blood Resources International at (800) 243-5759 for further evaluation.
- When thawing frozen products in a water bath, care must be taken to prevent contamination of entry ports. The use of watertight protective plastic over wraps (such as freezer bags) is recommended.
- 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).
- 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.
- 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, whichever is sooner. If blood or components cannot be infused in 4 hours, they should be divided 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, a crossmatch must be performed. **First time transfusions with donors and recipients of unknown blood types are NEVER considered safe.**
- Blood transfusions should never be considered 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 donor blood. Platelets and white blood cells in stored blood are nonviable. A single unit of Feline Whole Blood consists of approximately 45 mLs of whole blood with 7 mLs of anticoagulant collected from a donor with a minimum PCV of 32%.

Feline Whole Blood is currently collected in anticoagulant ACD-A. Other anticoagulants approved for the collection of whole blood are CPD, CP2D and CPDA-1. The refrigerated shelf life of the Whole Blood is determined by the type of anticoagulant used: ACD-A provides a shelf life of up to 28 days. This expiration date is indicated on the product label.

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 non labile coagulation properties.

FELINE WHOLE BLOOD AND BLOOD COMPONENTS

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. Stored Whole Blood cannot be considered a source of viable platelets, white cells or labile coagulation Factors V, Vlll or vWf.

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, 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 stored Whole Blood to correct coagulation deficiencies when they can be treated by appropriate components (see chart on page four).

Side Effects and Hazards

The principal side effects and hazards of Whole Blood are:

Hemolytic transfusion reactions occur when donor red blood cells and recipient plasma are incompatible. Undetected serologic incompatibilities can cause these reactions, but most immediate reactions occur when there is an erythrocyte based incompatibility. To reduce the risk of transfusion reactions a major and minor crossmatch should be conducted before every transfusion, even when blood is from the same donor and the donor and recipient are the same blood type.

The more severe transfusion reactions are characterized by shock, fever, dyspnea, jaundice, 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 and subsequent hyperbilirubinemia 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. Do not restart transfusion.

Delayed hemolytic reactions may also occur 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 a progressive, unexplained fall in hemoglobin up to 14 days after transfusion or continued anemia despite transfusion therapy. Fever, hemoglobinuria and/or hyperbilirubinemia may also be present. The usual course of delayed reactions is benign and requires no treatment. Rarely, delayed transfusion reactions may be severe or fatal.

Uncommon causes of acute non-immunologically mediated Hemolysis include administration of a hypotonic fluid, bacterial infection of the patient or contamination of the donor blood, acute hemolytic anemia from any cause or improper handling of the blood, such as overheating or freezing.

When hemolysed blood is transfused, the patient's course is usually benign, although hemoglobinuria, chills, DIC, renal failure and fever may occur. The characterization of and treatment for the infrequent severe reaction are the same as those for an immediate hemolytic transfusion reaction.

Transmission 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 be aggressive. Treatment should be initiated immediately after the collection of recipient blood samples for culturing. Treatment may include broad spectrum antimicrobials, vasopressors to maintain blood pressure and urinary flow, and intravenous fluid therapy to maintain fluid and electrolyte balance.

Alloimmunization of the recipient to red blood cell, white blood cell, platelet and protein antigens may be a consequence of transfusion. **Unlike canines, cats are born with antibodies that attack the red cells of incompatible cats.** This is known as reciprocal antibodies (i.e., cats that have type A are anti-B and cats that are type B are anti-A.). The A-B mismatch can result in immediate and possibly deadly transfusion reactions when incompatible blood is used. Even mild to severe reactions can influence recovery rates and can become serious.

Febrile reactions may occur rarely and are usually caused by antibodies that agglutinate leukocytes.

Allergic reactions manifested by urticaria, wheezing or other angioedematous reactions may occur rarely in recipients. The exact cause of many of these reactions is unknown; however, they are less frequent when Red Blood Cells are used instead of Whole Blood and may be prevented in patients with a prior history of such reactions by premedication of the patient with an antihistamine. Anaphylactic reactions manifested by bronchiospasm, dyspnea and pulmonary edema may occur in rare recipients. Immediate treatment with adrenaline and corticosteroids is indicated. These patients are not good candidates for further transfusions.

Circulatory overload reactions manifested by pulmonary edema occur when excessive volume is administered. This is a particular risk in older patients, in small patients, in patients with renal compromise and patients with chronic severe anemia when there is decreased red blood cell mass and increased plasma volume. Immediate treatment for pulmonary edema should be instituted.

Iron overload with resultant hemochromatosis is rare but may occur in patients given repeated transfusions over long periods of time.

Clinically significant depletion of coagulation proteins and platelets is a very rare complication of massive transfusion (defined as replacement of more than one blood volume in less than 24 hours). Careful monitoring of patients reveals that reduction of clotting factors below hemostatic levels is unusual but dilutional loss may occur. Treatment with specific components to replace reduced coagulation factors may be useful when bleeding is related to their depletion. If excessive bleeding occurs subsequent to a transfusion, the possibility of a hemolytic reaction complicated by DIC should be considered.

Micro aggregates consisting of fibrin, white cells and platelets may develop during storage of blood. The smallest of these particles will not be retained in a standard clot filter (170-260 μ).

Metabolic complications of transfusions can occur when very large amounts of blood, equal to or greater than the patient's blood volume, are rapidly infused, or when the patient has severe liver or kidney disease.

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.

Acidosis, which may occur initially during massive transfusion, rarely requires treatment. The citric acid is rapidly converted to pyruvate and bicarbonate, with subsequent metabolic alkalosis.

Dosage and Administration

Whole Blood should not be used unless donor and recipient are of the same blood type. 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 (0.11 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 Red Blood Cells rather than Whole Blood.

Components of Whole Blood

RED BLOOD CELLS

Description

The component Red Blood Cells (RBCs), is prepared by centrifugal or gravitational separation of the red cells from the plasma. The RBCs so processed yield approximately 15 mL± of red blood cells. The total fluid volume will be a minimum of 25 mL. Platelets and white blood cells are nonviable in stored blood products. RBC components are prepared from Whole Blood collected in ACD-A. A red cell nutrient solution is added back to the RBCs. This extends the shelf life up to one week beyond the shelf life of the whole blood from which they are derived. 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

Red Blood Cells is 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 hemorrhage. Hypovolemia without significant red cell mass deficit is best managed with volume expanders.

Contraindications

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

Side Effects and Hazards

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.

Dosage and Administration

The dosage and administration of Red Blood Cells are similar to those for Whole Blood. This product does not require the addition of sodium chloride to improve viscosity. 10 mL of red cell nutrient, AS-3, has been added back to the red cells. This provides increased shelf life and viscosity. Do not add lactated ringers or any other fluids with this product.

FRESH FROZEN PLASMA

Description

Fresh Frozen Plasma (FFP) is separated and frozen within 8 hours of collection of whole blood. **A Unit of Fresh Frozen Plasma contains the labile plasma coagulation Factors V and Vlll (including vWf).** Platelets, if present, are not viable. A standard unit contains a minimum of 25 mLs of FFP. Ranges are due to differences in donor PCV's.

Actions

FFP contains plasma proteins including all coagulation factors both labile and non 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 or not a problem. FFP may also be used in cases where Frozen Plasma is indicated. FFP is indicated for patients with thrombotic thrombocytopenic purpura (TTP).

Contraindications

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

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, non-cardiogenic pulmonary edema.

Dosage and Administration

A minor crossmatch should always be performed before plasma is administered. Plasma should be compatible with the recipient's red cells.

The volume transfused depends on the clinical situations and patient size. Some literature recommends 2 mL to 5mL 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 freezer bag) if a water bath is used. Microwaves are not recommended for thawing 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. Do not refreeze.

FROZEN PLASMA

Description

Frozen Plasma (FP) 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. FP contains a minimum of 25 mLs of Frozen Plasma. The range is 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

FP contains plasma proteins, including non labile clotting factors such as fibrinogen, Factor VII and Factor IX. FP does not contain the labile clotting Factors V, VIII and vWf.

Indications

These components are indicated for the treatment of stable clotting factor deficiencies, such as Warfarin poisoning, and plasma protein deficiencies. Note: Plasma is not the first treatment of choice for 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 vonWillebrand's 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 Fresh Frozen Plasma.

Dosage and Administration

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 coagula-tion factors. Frozen plasma thawed and maintained at temperatures of less than 45° F may be refrozen as long as closed system has not been breached.

REFERENCES

A reference list is available upon request from

Animal Blood Resources International, or on our website, www.abrint.net

www. ABRINT.net

(800) 243-5759

customerservice@abrint.net

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