DESCRIPTION
Albumin (Human) 20%, USP (Plasbumin®-20) is a made from large pools of human venous plasma by the Cohn cold ethanol fractionation process. Part of the fractionation may be performed by another licensed manufacturer. It is prepared in accordance with the applicable requirements established by the U.S. Food and Drug Administration.

Plasbumin-20 is a 20% sterile solution of albumin in an aqueous diluent. The preparation is stabilized with 0.016 M sodium caprylate and 0.016 M sodium hydroxide. The aluminum content of the product is not more than 200 µg/mL. The sodium content of the product is 145 mmol/L. Plasbumin-20 is clear, slightly viscous, almost colorless to pale yellow, amber or green. It contains no preservatives. Plasbumin-20 must be administered intravenously.

CLINICAL PHARMACOLOGY
Each vial of Plasbumin-20 is heat-treated at 60°C for 10 hours against the possibility of transmitting the hepatitis virus. Additionally, the manufacturing process was investigated for its capacity to decrease the infectivity of an experimental agent of transmissible spongiform encephalopathy (TSE), considered a model for the variant Creutzfeldt-Jakob disease (vCJD) and Creutzfeldt-Jakob disease (CJD) agents.(11-14) The production steps from Pooled Plasma to Effluent IV-1 in the Plasbumin-20 manufacturing process have been shown to decrease TSE infectivity of that experimental model agent to a total of >7.0 logs. These studies provide reasonable assurance that low levels of vCJD/CJD agent infectivity, if present in the starting material, would be removed.

Indications and Usage
Emergency Treatment of Hypovolemic Shock
Plasbumin-20 is hyperoncotic and on intravenous infusion will expand the plasma volume by an additional amount, three to four times the volume actually administered, by withdrawing fluid from the interstitial spaces, provided the patient is normally hydrated interstitially or there is interstitial edema (1) if the patient is dehydrated, additional crystalloids must be given (2) or alternatively, Albumin (Human) 5%, USP (Plasbumin-5®) should be used. The patient’s hemodynamic response should be monitored and the usual precautions against circulatory overload observed. The total dose should not exceed the level of albumin found in the normal individual; i.e., about 2 g per kg body weight in the absence of acute bleeding. Although Plasbumin-5 is to be preferred for the usual volume deficits, Plasbumin-20 with appropriate crystalloids may offer therapeutic advantages in oncotic deficits or in long-standing shock or in shock states that occur in resuscitation of the burn victim. Plasbumin-20 is a protein transport and it may be useful in severe hemoconcentration, in the neonate who is awaiting exchange transfusion, the infused albumin may reduce the level of free bilirubin in the blood (2,3) This is somewhat helpful in adult liver failure where albumin might serve the dual role of supporting plasma oncotic pressure, as well as binding excessive plasma bilirubin (2)

Burn Therapy
An optimal therapeutic regimen with respect to the administration of colloids, crystalloids, and water following extensive burns has not been established. During the first 24 hours after sustaining thermal injury large volumes of crystalloids are infused to restore the depleted extracellular fluid volume. Beyond 24 hours Plasbumin-20 can be used to maintain plasma colloid osmotic pressure.

Hypoproteinemia With or Without Edema
During major surgery, patients can lose or have lost over half of their circulating albumin with the attendant complications of oncotic deficit (2,4,5) a similar situation can occur in interscapular or intensive care patients. Treatment with Plasbumin-20 may be of value in such cases (2).

Adult Respiratory Distress Syndrome (ARDS)(2,5)
This is characterized by deficient oxygenation caused by pulmonary interstitial edema complicating shock and postcardiovascular conditions. When clinical signs are those of hypoproteinemia with a fluid volume overload, Plasbumin-20 together with a diuretic may play a role in therapy.

Cardiopulmonary Bypass(2,6)
With the relatively small priming volume required with modern pumps, preoperative dilution of the blood using albumin and crystalloid has shown to be safe and well-tolerated. Although there is no evidence for a threshold, in general, it is recommended not to use less than 1 g/kg. Although a concentration can be safely lowered has not been defined, it is common practice to adjust the albumin and crystalloid pump prime to achieve a hematocrit of 20% and a plasma albumin concentration of 2.5 g per 100 mL in the patient.

Acute Liver Failure(2)
In the uncommon situation of rapid loss of liver function with or without coma, administration of albumin may serve the double purpose of supporting the coagulation system of the plasma as well as binding excess plasma bilirubin.

Neonatal Hemolytic Disease(2,3)
The administration of Plasbumin-20 may be indicated prior to exchange transfusion, in order to bind free bilirubin, thus assuring the risk of kernicterus. A dosage of 1 g/kg body weight is given about 1 hour prior to exchange transfusion. Caution must be observed in hyperbilirubinemic infants.

Sequestration of Protein Rich Fluids(7)
This occurs in such conditions as acute peritonitis, pancreatitis, mediastinitis, and extensive cellulitis. The magnitude of fluid loss into the third space may require treatment of reduced volume or oncotic activity with an infusion of albumin.

Erythrocyte Resuspension(2)
Albumin may be required to avoid excessive hypoproteinemia during certain types of exchange transfusion, or with the use of very large volumes of previously frozen or washed red cells. About 25 g of albumin per liter of erythrocytes is commonly used, although the requirements in premature hypoproteinemia or hepatic impairment can be greater. Plasbumin-20 is added to the isotonic suspension of washed red cells immediately prior to transfusion.

Acute Nephrosis(2)
Certain patients may not respond to cyclophosphamide or steroid therapy. The steroids may even aggravate the underlying edema. In this situation a loop diuretic and 100 mL Plasbumin-20 repeated daily for 7 to 10 days may be helpful in controlling the edema and the patient may then respond to steroid treatment.

Renal Dialysis(2)
Although not part of the regular regimen of renal dialysis, Plasbumin-20 may be of value in the treatment of shock or hypoproteinemia in these patients. The usual volume administered is about 100 mL, taking special care to avoid fluid overload as these patients are often fluid overloaded and cannot tolerate substantial volumes of salt solution.

Situations in Which Albumin Administration is Not Warranted(2)
In chronic nephrosis, infused albumin is promptly excreted by the kidneys with no relief of the chronic edema or effect on the underlying renal lesion. It is of occasional use in the rapid “priming” diuresis of nephrosis. Similarly, in hypoproteinemic states associated with chronic cirrhosis, malabsorption, protein-losing enteropathies, pancreatic insufficiency, and undernutrition, the infusion of albumin as a source of protein nutrition is not justified.

Contraindications
Certain patients, e.g., those with a history of congestive cardiac failure, renal insufficiency or stabilized chronic anemia, are at special risk of developing circulatory overload. A history of an allergic reaction to albumin is a specific contra- indication to usage.

WARNINGS
Plasbumin-20 is made from human plasma. Products made from human plasma may contain infectious agents, such as viruses, and, theoretically, the Creutzfeldt-Jakob Disease (CJD) agent that can cause disease. The theoretical risk for transmission of CJD is considered extremely remote. No cases of transmission of viral diseases or CJD have ever been identified for albumin. The risk that such products will transmit an infectious agent has been reduced by screening plasma donors for prior exposure to certain viruses, by testing for the presence of certain current virus infections, and by inactivating and/or removing certain viruses. Despite these measures, such products can still potentially transmit disease. There is also the possibility that unknown infectious agents may be present in such products. Individuals who receive infusions of blood or plasma products may develop signs and/or symptoms of some
viral infections, particularly hepatitis C. ALL infections thought by a physician possibly to have been transmitted by
plasma derived products should be reported to the Centers for Disease Control and Prevention. (See section on Adverse
Reactions).

ANIMAL REPRODUCTION STUDIES

Animal reproduction studies have not been conducted with Plasbumin-20.

PEDIATRIC USE

Pediatric use is warranted only when clearly needed.

ADVERSE REACTIONS

Adverse reactions to albumin are rare. Such reactions may be allergic in nature or due to high plasma protein levels from
excessive albumin administration. Allergic manifestations include urticaria, chills, fever, and changes in respiration, pulse
and blood pressure.

DOSAGE AND ADMINISTRATION

Plasbumin-20 should always be administered by intravenous infusion. Plasbumin-20 may be administered either undiluted
or at a dilution of 10% Sodium Chloride or 5% Dextrose in Water. If sodium restriction is necessary, only a 5% Dextrose
solution should be used. It should be administered either undiluted or diluted in a sodium-free carbohydrate solution such as
5% Dextrose in Water.

A number of factors beyond our control could reduce the efficacy of this product or even result in an anaphylactic
reaction. These include improper storage and handling of the product after it leaves our hands, diagnosis, dosage, method of
administration, and biological differences in individual patients. Because of these factors, it is important that this product
be stored properly and that the directions be followed carefully during use.

Hypervolemic Shock — For treatment of hypervolemic shock, the volume administered and the speed of infusion should be
adapted to the response of the individual patient.

Burns — After a burn injury (usually beyond 24 hours) there is a close correlation between the amount of albumin infused and
the rise in plasma colloidal osmotic pressure. The aim should be to maintain the plasma albumin concentration in the
region of 2.5 — 0.5 g per 100 mL with a plasma oncotic pressure of 20 mm Hg. However, diagnosis, dosage, method of
administration, and biological differences in individual patients. Because of these factors, it is important that this product
be stored properly and that the directions be followed carefully during use.

Drug Interactions

Plasbumin-20 is compatible with whole blood, packed red cells, as well as the standard carbohydrate and electrolyte
solutions intended for intravenous use. It should, however, not be mixed with protein hydrolysates, amino acid solutions
for those-containing alcohol.

Pregnancy Category C

Animal reproduction studies have not been conducted with Plasbumin-20. It is also not known whether Plasbumin-20 can
cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Plasbumin-20 should be
given to a pregnant woman only if clearly needed.

Pediatric Use

Safety and effectiveness in the pediatric population have not been established.

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