CSL Behring

Albumin (Human) USP, 5%
Albuminar®-5

℞ only

DESCRIPTION

Albumin (Human) 5%, Albuminar®-5 is a sterile solution of albumin obtained from large pools of adult human venous plasma by low temperature controlled fractionation according to the Cohn process. It is heated at 60°C for 10 hours and stabilized with 0.004 M sodium acetyltryptophanate and 0.004 M sodium caprylate.

All Source Plasma used in the manufacture of this product was tested by FDA-licensed Nucleic Acid Testing (NAT) for HBV, HCV, and HIV-1 and found to be nonreactive (negative).

Each 50 mL vial of 5% solution contains 2.5 grams of albumin in normal saline. Each 250 mL bottle of 5% solution contains 12.5 grams of albumin in normal saline. Each 500 mL bottle of 5% solution contains 25 grams of albumin in normal saline. The 5% solution is osmotically equivalent to citrated plasma. The pH of the solution is adjusted to 6.9 ± 0.5 with sodium bicarbonate, sodium hydroxide, or acetic acid. Approximate concentrations of significant electrolytes per liter are: sodium 130-160 mEq; and potassium-n.m.t. 1 mEq. The solution contains no preservative. This product has been prepared in accordance with the requirements established by the Food and Drug Administration and is in compliance with the standards of the United States Pharmacopeia.

Albuminar®-5 is to be administered by the intravenous route.

The heat treatment step employed in the manufacture of Albuminar®-5 pasteurization of the final container at 60ºC for 10 hours, has been validated in a series of *in vitro* experiments for its capacity to inactivate Human Immunodeficiency Virus type 1 (HIV-1), and the following model viruses: Bovine Viral Diarrhea Virus (BVDV - an enveloped virus used as a model for hepatitis C virus), Pseudorabies (PrV - a large, enveloped virus), and Encephalomyocarditis Virus (EMC - a small non-enveloped virus). For each virus studied, three independent experiments were conducted using Albuminar®-5 and Albumin (Human) 25%, Albuminar®-25 with the following results.[1]

Pasteurization (60°C for 10 hours) Viral Reduction Studies (log_{10} reduction)	
Virus	Albumin (Human) 5%, Albuminar®-5
HIV-1	>5.44, >6.38 and >6.31
BVDV	>6.01, >6.76 and >6.55
PrV	>7.30, >7.68 and >7.63
EMC	>7.38, >7.97 and >7.97
Virus	Albumin (Human) 25%, Albuminar®-25
HIV-1	>5.50, >6.57 and >6.64
BVDV	>5.99, >5.81 and >5.32
PrV	>7.32, >7.20 and >7.42
EMC	>7.10, >7.89 and >7.87

CLINICAL PHARMACOLOGY

Albuminar®-5, being active osmotically, is useful in regulating the volume of circulating blood. It is a valuable therapeutic aid for the treatment of conditions that will be benefited by its marked osmotic effect. When the circulating blood volume has been depleted, the hemodilution following albumin administration persists for many hours. In individuals with normal blood volume, it usually lasts only a few hours.

Albumin (Human), unlike whole blood or plasma, is considered free of the danger of viral hepatitis because it is heated at 60ºC for 10 hours. It is convenient to use since no cross-matching is required and the absence of cellular elements removes the danger of sensitization with repeated infusions.

INDICATIONS AND USAGE

SHOCK - Albuminar®-5 is indicated in the emergency treatment of shock due to burns, trauma, operations and infections, in the treatment of severe injuries, and in other similar conditions where the restoration of blood volume is urgent. The primary function is maintenance of colloid osmotic pressure. If there has been considerable loss of red blood cells, transfusion with packed red blood cells is indicated.

BURNS - Albuminar®-5 is indicated in conjunction with adequate infusions of crystalloid to counteract hemoconcentration and the loss of protein, electrolytes and water that usually follow severe burns. Because of changes in permeability, little administered albumin is likely to be retained intravenously in the first 12 hours after a major burn. However, an optimum regimen for the use of colloid, electrolytes and water in the treatment of burns has not been established.

HYPOPROTEINEMIA - Albuminar®-5 may be used in acutely hypoproteinemic patients, provided sodium restriction is not a problem.

CONTRAINDICATIONS

Albuminar®-5 is contraindicated in patients with severe anemia or cardiac failure and in patients with a history of allergic reactions to human albumin.

WARNINGS

Do not use if the solution is turbid or if there is a sediment in the bottle. Since the product contains no antimicrobial preservative, do not begin administration more than 4 hours after the container has been entered. Destroy unused portions to prevent the possibility of subsequent use of a solution that may have become contaminated.

Albuminar®-5 is made from human plasma. Products made from human plasma may contain infectious agents such as viruses, that can cause disease. 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 during manufacture. The manufacturing procedure for Albuminar®-5 includes processing steps designed to reduce further the risk of viral transmission. Stringent procedures utilized at plasma collection centers, plasma testing laboratories, and fractionation facilities are designed to reduce the risk of viral transmission. Albuminar®-5 is pasteurized in the final container at 60.0 +/- 0.5ºC for 10-11 hours. Virus elimination/inactivation is also achieved by the cold alcohol fractionation process. (See **DESCRIPTION** section for further information on viral reduction measures.) Despite these measures, such products may still potentially contain human pathogenic agents, including those not yet known or identified. Thus the risk of transmission of infectious agents cannot be totally eliminated. Any infections thought by a physician possibly to have been transmitted by this product should be reported by the physician or other healthcare provider to CSL Behring at 1-866-915-6958. The physician should discuss the risks and benefits of this product with the patient.

Albumin is a derivative of human blood. Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases. A theoretical risk for transmission of Creutzfeldt-Jakob disease (CJD) also is considered extremely remote. No cases of transmission of viral diseases or CJD have ever been identified for albumin.

PRECAUTIONS

GENERAL

Administration of large quantities of albumin should be supplemented with red blood cells or replaced by whole blood to combat the relative anemia which would follow such use. The quick response of blood pressure, which may follow the rapid administration of albumin, necessitates careful observation of the injured patient to detect bleeding points which failed to bleed at lower blood pressure. Albuminar®-5 should be administered with caution to patients with low cardiac reserve or with no albumin deficiency because a rapid increase in plasma volume may cause circulatory compromise (e.g. hypertension, hypotension, or pulmonary edema). In cases of hypertension, a slower rate of administration is desired. Albuminar®-5 may be administered at a rate of 10 grams of albumin (200 mL) per hour.

If anaphylactic or severe anaphylactoid reactions occur, discontinue infusion immediately. Infusion rates and the patient's clinical state should be monitored closely during infusion.

INFORMATION FOR PATIENT - Some viruses, such as parvovirus B19 or hepatitis A are particularly difficult to remove or inactivate at this time. Parvovirus B19 may most seriously affect pregnant women, or immune-compromised individuals. The majority of parvovirus B19 and hepatitis A infections are acquired by environmental (community acquired) sources.

PREGNANCY CATEGORY C - Animal reproduction studies have not been conducted with Albuminar®-5. It is also not known whether Albuminar®-5 can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Albuminar®-5 should be given to a pregnant woman only if clearly needed.

PEDIATRIC USE - No clinical studies using Albuminar®-5 have been conducted in pediatric patients. Safety and effectiveness in pediatric patients have not been established. However, extensive experience in patients suggests that children respond to Albuminar®-5 in the same manner as adults.

ADVERSE REACTIONS

The incidence of untoward reactions to Albuminar®-5 is low. Reports have been received of anaphylaxis, which may be severe, and hypersensitivity reactions (including urticaria, skin rash, pruritus, edema, erythema, hypotension and bronchospasm). Nausea, vomiting, increased salivation, chills and febrile reactions have also been reported (see also **PRECAUTIONS**).

DOSAGE AND ADMINISTRATION

Albuminar®-5 may be given intravenously without further dilution. This concentration is approximately isotonic and iso-osmotic with citrated plasma. Albumin (Human) in this concentration provides additional fluid for plasma volume expansion. Therefore, when it is administered to patients with normal blood volume, the rate of infusion should be slow enough to prevent too rapid expansion of plasma volume.

In the treatment of shock in an adult patient an initial dose of 500 mL of the 5% albumin solution is given as rapidly as tolerated. If response within 30 minutes is inadequate, an additional 500 mL of 5% albumin solution may be given. The 50 mL dosage form would be appropriate for pediatric use, with a dose of 10-20 mL per kg of body weight infused intravenously at a rate up to 5-10 mL per minute. Therapy should be guided by the clinical response, blood pressure and an assessment of relative anemia. If more than 1000 mL are given, or if hemorrhage has occurred, the administration of packed red blood cells may be desirable.

In severe burns, immediate therapy should include large volumes of crystalloid with lesser amounts of 5% albumin solution to maintain an adequate plasma volume. After the first 24 hours, the ratio of albumin to crystalloid may be increased to establish and maintain a plasma albumin level of about 2.5 g/100 mL or a total serum protein level of about 5.2 g/100 mL. However, an optimal regimen for the use of colloids, electrolytes and water after severe burns has not been established.

The infusion of Albumin (Human) as a nutrient in the treatment of chronic hypoproteinemia is not recommended. In acute hypoproteinemia, 5% albumin may be used in replacing the protein lost in hypoproteinemic conditions. However, if edema is present or if large amounts of albumin are lost, Albumin (Human) 25% is preferred because of the greater amount of protein in the concentrated solution.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

HOW SUPPLIED

Albuminar®-5 is supplied as a 5% solution. Each product presentation includes a package insert and the following component:

Presentation	Carton NDC Number	Component
50 mL	0053-7670-06	One vial containing 2.5 grams of albumin (NDC 0053-7670-90)
250 mL	0053-7670-31	One bottle containing 12.5 grams of albumin (NDC 0053-7670-91)
500 mL	0053-7670-32	One bottle containing 25 grams of albumin (NDC 0053-7670-92)

Store between 20-25ºC (68-77ºF); excursions permitted to 15-30ºC (59-86ºF) [See USP Controlled Room Temperature].

REFERENCES

1. Data on file.

BIBLIOGRAPHY

Finlayson, J.S.: Albumin Products. *Seminars in Thrombosis and Hemostasis* 6:85-120, 1980.

Tullis, J.L.: Albumin. *JAMA* 237: 355-360 and 460-463, 1977.

Rudolph, A.M.: Pediatrics. 18th ED., p. 1839, Appleton and Lange, 1987.

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