HUMAN ALBUMIN 20% I.P.

Hemalb®

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DESCRIPTION: Hemalb 20% is a nonpyrogenic, sterile aqueous solution of Human Albumin I.P. for intravenous administration and is purified from pooled human venous plasma using a series of chromatography steps. Each 100 mL bottle contains 20 g of Albumin stabilized with N-acetyltryptophan (not more than 0.08 mmol/g of protein) and Sodium caprylate (not less than 0.08 mmol/g of protein) in a solution that has been adjusted to physiological pH with sodium hydroxide. The sodium content in the solution is not more than 160 mmol/L and the potassium content is not more than 2 mmol/L. The aluminum content is not more than 200 µg/L. It is clear, slightly viscous and greenish-yellow or amber to green in colour and does not contain preservative or antimicrobial agent.

COMPOSITION: Each 100 mL **Hemalb 20%** bottle contains

Total Protein	200 g/L
N-Acetyltryptophan	Not more than 0.08 mmol/g of protein.
Sodium caprylate	Not less than 0.08 mmol/g of protein.
Na content	Not more than 160 mmol/L
K content	Not more than 2 mmol/L
Aluminum content	Not more than 200 µg/L

Hemalb 20% is produced from pooled human plasma for fractionation conforming to the highest standards set forth by regulatory authorities. In addition, the plasma donor units and the production plasma pool are tested negative using NAT approved by regulatory authorities for HIV 1 & 2, HCV and HBV.

The manufacturing process incorporates multiple dedicated orthogonal viral inactivation / removal steps ensuring safety of the product. Viral inactivation is carried out in two dedicated steps. The first step is *caprylate/low pH incubation for* 10-12 hours at 30°C, pH 4.5 and the second step is *Pasteurization* for 10 hours at 60°C.

CLINICAL PHARMACOLOGY: Albumin accounts for 70-80% of the colloidal osmotic pressure of plasma involved in regulating the circulating blood volume and this is the primary reason for its clinical use. In addition, it also functions as a carrier protein for several hydrophobic steroid hormones and fatty acids. Human Albumin is highly stable, globular protein of molecular weight 66,500 Daltons. The total body albumin in a 70 kg man is approximately 320 g. It is distributed throughout the extracellular compartments and more than 60% of the body albumin pool is located in the extravascular fluid compartment. Albumin has a circulating life span of 15-20 days with a turnover of approximately 15 g per day.

Human Albumin 20% provides the oncotic equivalent of approximately four times its volume of human plasma. It will increase the circulating plasma volume by an amount approximately three times the volume infused within 15 minutes when the patient is adequately hydrated.

This extra fluid reduces hemoconcentration and decreases blood viscosity. The degree and duration of volume expansion depends upon the initial blood volume. When treating patients with diminished blood volume, the effect of infused albumin may persist for many hours. The hemodilution lasts for a shorter time when albumin is administered to individuals with normal blood volume.

INDICATIONS AND USAGE: Human Albumin 20% is indicated to maintain and restore circulating blood volume in many clinical conditions including:

1) Hypovolemia: Hypovolemia is a possible indication for use of Human Albumin 20%. Its effectiveness in reversing hypovolemia depends largely upon its ability to draw interstitial fluid into the circulation. It is most effective with patients who are well hydrated.

2) Hypoalbuminemia:

A) General: Hypoalbuminemia is another possible indication for use of Human Albumin 20%. Hypoalbuminemia can result from one or more of the following: 1) Inadequate production (malnutrition, burns, major injury, infections, etc.) 2) Excessive catabolism (burns, major injury, pancreatitis, etc.) 3) Loss from the body (hemorrhage, excessive renal excretion, burn exudates, etc.) 4) Redistribution within the body (major surgery, various inflammatory conditions, etc.)

B) Burns: An optimum regimen for the use of albumin, electrolytes and fluid in the early treatment of burns has not been established, however, in conjunction with appropriate crystalloid therapy, Human Albumin 20% may be indicated for treatment of oncotic deficits after the initial 24-hour period following extensive burns and to replace the protein loss which accompanies any severe burn.

C) Adult Respiratory Distress Syndrome (ARDS): Characteristic of ARDS is a hypoproteinemic state, which may be causally related to the interstitial pulmonary edema. Although uncertainty exists concerning the precise indication of albumin infusion in these patients, if there is a pulmonary overload accompanied by hypoalbuminemia, Human Albumin 20% may have a therapeutic effect when used with a diuretic.

D) Acute Nephrosis: Human Albumin 20% may be useful aid in treating edema in patients with severe nephrosis who are receiving steroids and/or diuretics.

3) Renal Dialysis: Patients undergoing long-term hemodialysis may be administered Human Albumin 20% for the treatment of a volume or an oncotic deficit.

4) Hemolytic Disease of the Newborn (HDN): Human Albumin 20% may be administered in an attempt to bind and detoxify unconjugated bilirubin in infants with severe HDN.

5) Cardiopulmonary Bypass Surgery: Human Albumin 20% has been recommended prior to or during cardiopulmonary bypass surgery, although no clear data exist indicating its advantage over crystalloid solutions.

CONTRAINDICATIONS: Human Albumin 20% is contra-indicated in patients with a history of allergic reactions to albumin and any of the excipients. Human Albumin 20% is also contraindicated in severely anaemic patients and in patients with cardiac failure.

Human Albumin 20% must not be diluted with Sterile Water for Injection as this may cause hemolysis in recipients. Acceptable diluents include 0.9% Sodium Chloride or 5% Dextrose in Water.

Human Albumin 20% must not be administered to patients with chronic renal insufficiencies due to the potential for accumulations of aluminum that may lead to toxic manifestations such as hypercalcemia, vitamin D-refractory osteodystrophy, anaemia and severe progressive encephalopathy.

WARNINGS: The risk that Human Albumin 20% will transmit an infectious agent is extremely remote since the process involves stringent screening of 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. The measures taken are considered effective for enveloped viruses such as HIV, HBV, and HCV, and for the non-enveloped viruses HAV and Parvovirus B19.

PRECAUTIONS:

1. Hemodynamics: Do not administer Human Albumin 20% without very close monitoring of hemodynamics; look for evidence of cardiac or respiratory failure, renal failure or increasing intra-cranial pressure.

2. Hypervolemia/Hemodilution: Human Albumin 20% should be used with caution in conditions where hypervolemia and its consequences or hemodilution could represent a special risk for the patient.

3. Blood pressure: A rapid rise in blood pressure following Human Albumin 20% infusion necessitates careful observation of injured or post-operative patients to detect and treat severed blood vessels that may not have bled at a lower blood pressure.

4. Large Volume: Control of Coagulation and Hematocrit are necessary when comparatively large volumes are to be replaced.

5. Electrolyte Status: When Human Albumin 20% is administered, the electrolyte status of the patient should be monitored and appropriate steps taken to restore or maintain the electrolyte balance.

USE IN SPECIAL POPULATION:

Pregnancy: There are no sufficient data from the use of Human Albumin 20% in pregnant or lactating women. Hence, physicians should carefully consider the potential risks and benefits for each specific patient before prescribing Human Albumin 20% and should be given to a pregnant woman only if clearly needed.

Pediatric Use: The pediatric use of Human Albumin 20% has not been clinically evaluated. The dosage will vary with the clinical state and body weight of the individual.

ADVERSE REACTIONS: The most common adverse reactions include fever and chills, rash, nausea, vomiting, tachycardia and hypotension.

Whenever an adverse reaction occurs, stop or slow the infusion for a short period of time which may result in the disappearance of the symptoms. If administration has been stopped and the patient requires additional Albumin, material from a different lot should be used. Albumin, particularly if administered rapidly, may result in vascular overload with resultant pulmonary edema.

DOSAGE AND ADMINISTRATION: Human Albumin 20% is administered intravenously. The total dosage will vary with the individual. In adults, an initial infusion of 100 mL is suggested. Additional amounts may be administered as clinically indicated. Human Albumin 20%, particularly if administered rapidly, may result in vascular overload with resultant pulmonary edema.

Daily dose should not exceed 2 g of Albumin per kg body weight. Human Albumin 20% is hyper osmotic and should be given by slow intravenously infusion at a rate of about 1 mL per minute. The rate of infusion and the total volume of Human Albumin 20% administered ultimately must be guided by the haemodynamic response of the patient and the clinical indication for which it has been prescribed. When Human Albumin 20% is infused, a rise in blood pressure necessitates careful observation to detect and treat severed blood vessels that may not have bled at a lower blood pressure.

Do not use unless the seal is intact.

Contents must be used within 4 hours after opening and any unused solution is to be discarded carefully.

Dilute with 0.9% Sodium Chloride or 5% Dextrose in Water.

Do not use Sterile Water for Injection as a diluent.

DO NOT FREEZE.

Large volumes and rapid infusion may cause signs and symptoms of hypervolemia. Stop the infusion immediately. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

STORAGE: Store **Hemalb 20%** between 2°C and 25°C.

Do not freeze, Protect from light. Keep out of reach of children.

SHELF LIFE: Hemalb 20% is stable for three years from the date of manufacturing at recommended storage conditions.

IMPORTANT INFORMATION:

The product is not to be used if it is cloudy or if a deposit has formed. Adverse reactions to Human Albumin 20% are extremely rare, although nausea, fever, chills or urticaria may occasionally occur. Such symptoms usually disappear when the infusion is slowed or stopped for short period of time.

Manufactured and Marketed by:

ICHOR
Biologics Pvt. Ltd.
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