DOSAGE AND ADMINISTRATION
Human Albumin I.P. 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.
Intravenous Use Only. Human Albumin I.P. 20%, particularly if administered rapidly, may result in vascular overload with resultant pulmonary edema.

Daily dose should not exceed 2 g per kg body weight.
Do not dilute with sterile water for injection as this may cause hemolysis in recipients.
Large volumes and rapid infusion may cause signs and symptoms of hypervolaemia. Stop the infusion immediately.
Reconstitute with 0.9% Sodium Chloride or 5% Dextrose in Water. Do not use Sterile Water for Injection as a diluent. Do not freeze.

PREPARATION FOR ADMINISTRATION
Do not use unless solution is clear of particulate matter and seal is intact. Hemalb 20 % is a transparent or slightly opalescent solution, which may vary from a pale yellow to straw color. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.
1. Remove cap from bottle to expose center portion of rubber stopper.
2. Clean stopper with germicidal solution.

STORAGE
Store Human Albumin I.P. 20% at 2°C to 25 °C.
Do not freeze. Protect from light. Keep away from children.
Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration.

SHELF LIFE
Human Albumin I.P. 20% is stable for three years from the date of manufacturing at recommended storage conditions.

Important Information:
Human Albumin 20% is contraindicated in patients with a history of allergic reactions to human albumin.
Do not use if the solution is turbid on tampered.
Human Albumin 20% is hyper osmotic and should be given by slow intravenous infusion at a rate of about 1 mL per minute.
The rate of infusion and the total volume of Human Albumin I.P. 20% administered ultimately must be guided by the haemodynamic response of the patient and the clinical indication for which it has been prescribed.
Reconstitute with 0.9% Sodium Chloride or 5% Dextrose in Water. Do not use Sterile Water for Injection as a diluent.
Human Albumin 20% must be administered intravenously at a rate not to exceed 1ml/min to patients with normal blood volume, due to the risk of developing circulatory overload and pulmonary edema.
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.
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 a short period of time.

Manufactured and Marketed by:
Hemarus Therapeutics Limited
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HUMAN ALBUMIN 20 % I.P.

Hemalb™
Human albumin 20% I.P.

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 vial contains 20 g of Albumin stabilized with N- Acetyl tryptophan (0.016 M) and sodium caprylate (0.016 M) in a solution that has been adjusted to physiological pH with sodium hydroxide. The sodium content in the solution is 145 ± 15 mEq/L and the potassium content is not more than 2mEq/L. The aluminium content is NMT 200 µg/L. It is clear, slightly viscous and straw yellow in colour and do not contain preservative or antimicrobial agent.

COMPOSITION

Each 100 mL Hemalb 20 % vial contains

Total Protein	200 g/L
N-Acetyl tryptophan	0.016 M
Sodium Caprylate	0.016 M
Na^+ Content	145 ± 15 mEq/L
K^+ Content	≤2m Eq/L
Aluminium Content	≤ 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 HIV1& 2, HCV and HBV.
The manufacturing process incorporates multiple dedicated orthogonal viral inactivation and removal steps ensuring safety of the product.Viral inactivation is carried out in three dedicated steps. The first step is heat treatment followed by ***Caprylate/low pH incubation*** for 10-12 hours at 30̊C, pH 4.5 and the other two steps are ***Pasteurization-I of the formulated bulk and Pasteurization –II of the filled vials*** for 10hrs at 60̊C, pH 7.0.

CLINICAL PHARMACOLOGY

Albumin accounts for 70-80% of the colloid 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 a highly stable and globular protein of molecular weight 66,500. 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 I.P. 20% is also contraindicated in severely anaemic patients and in patients with cardiac failure

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

WARNINGS

The risk that Human Albumin I.P. 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 I.P. 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 I.P. 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 I.P. 20% infusion necessitates careful observation of injured or postoperative patients to detect and treat severed blood vessels that may not have bled at a lower 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 I.P. 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 I.P. 20% in pregnant or lactating women. Hence, physicians should carefully consider the potential risks and benefits for each specific patient before prescribing Human Albumin I.P. 20% and should be given to a pregnant woman only if clearly needed.

Pediatric Use

The pediatric use of Human Albumin I.P. 20% has not been clinically evaluated. The dosage will vary with the clinical state and body weight of the individual. Typically, a dose one-quarter to one-half the adult dose may be administered, or dosage may be calculated on the basis of 0.6 to 1.0 gram per kilogram of body weight.

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.

Human Albumin I.P. 20% provides the oncotic equivalent of approximately 4 times its volume of human plasma. It will increase the circulating plasma volume by an amount approximately 3.0 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 depend 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 I.P. 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 I.P. 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.
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2.Hypoalbuminemia
A. General: Hypoalbuminemia is another possible indication for use of Human Albumin I.P. 20% solution. 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 I.P. 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 I.P. 20% solution may have a therapeutic effect when used with a diuretic.

D. Acute Nephrosis. : Human Albumin I.P. 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 20% Human Albumin I.P. solution for the treatment a volume or an oncotic deficit.

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

CONTRAINDICATIONS

Human Albumin I.P. 20% is contraindicated in patients with a history of allergic reactions to albumin and any of the excipients.