Biocon

Human Normal Albumin IP 20% & 5%

ALBUBET® /ALBUBET® 5% एलबुबेट/एलबुबेट ५%

ALBUBET®
Composition:
Each Vial contains:

Total Protein	200 g/Lit
Sodium Caprylate	6.65 g/Lit
Na^+ Not more than	160 mmol/Lit
K^+ Not more than	2 mmol/Lit
Aluminium	≤ 200 µg/Lit

ALBUBET® 5%
Composition:
Each Vial contains:

Total Protein	50 g/Lit
Sodium Caprylate	1.66 g/Lit
Na^+ Not more than	160 mmol/Lit
K^+ Not more than	2 mmol/Lit
Aluminium	≤ 200 µg/Lit

DESCRIPTION
ALBUBET® & ALBUBET® 5% Solutions are a sterile, nonpyrogenic preparations of human albumin in a single dose container for intravenous administration. Each 100 mL contains 20g & 5g of albumin respectively and is prepared from qualified human plasma. The process includes several chromatographic steps and viral inactivation steps.

The manufacturing process uses plasma collected from the donors who are screened for their history as per guidelines laid down by the regulatory authorities. Their blood is screened for the mandatory infectious diseases. Only on being declared negative to HbsAg, HCV and HIV antibodies the plasma is used for processing.

CLINICAL PHARMACOLOGY
Albumin is a highly soluble, globular protein (molecular weight 66,500), accounting for 70-80% of the colloid osmotic pressure of plasma. Therefore, albumin is important in regulating the osmotic pressure of plasma. Human Normal Albumin 20% and 5% solution will increase the circulating plasma volume. This extra fluid reduces haemoconcentration and decreases blood viscosity. The degree and duration of volume expansion depends upon the initial blood volume. With patients treated for diminished blood volume, the effect of infused albumin may persist for many hours; however, in patients with normal volume, the duration will be shorter.

INDICATIONS
Hypovolaemic shock: Albumin is indicated in the treatment of hypovolaemic shock associated with blood loss, trauma and surgical procedures.

Hypoalbuminemia
General
Hypoalbuminemia is another possible indication for use of **ALBUBET® & ALBUBET® 5%**.
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.)

When albumin deficit is the result of excessive protein loss, the effect of administration of albumin will be temporary unless the underlying disorder is reversed. In most cases, increased nutritional replacement of amino acids and/or protein with concurrent treatment of the underlying disorder will restore normal plasma albumin levels more effectively than albumin solutions.

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, Albumin 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.

Hemolytic Disease of the Newborn (HDN)
Albumin 20% may be administered in an attempt to bind and detoxify unconjugated bilirubin in infants with severe HDN.
There is no valid reason for use of albumin as an intravenous nutrient.

Miscellaneous Indications
ALBUBET® 5%, may be indicated prior to or during cardiopulmonary bypass surgery, though the data do not indicate a clear-cut advantage over crystalloid solutions.

CONTRAINDICATIONS
A history of allergic reactions to albumin and any of the excipients is a specific contraindication to the use of this product. Albumin is also contraindicated in severely anemic patients and in patients with cardiac failure.

WARNINGS
Do not use if turbid. Do not begin administration more than 4 hours after the container has been opened. Discard unused portion. There exists a risk of potentially fatal hemolysis and acute renal failure from the inappropriate use of Sterile Water for Injection as a diluent for **ALBUBET® & ALBUBET® 5%**. Acceptable diluents include 0.9% Sodium Chloride or 5% Dextrose in Water.

Hypersensitivity
Hypersensitivity or allergic reactions have been observed, and may in some cases progress to severe anaphylaxis. Epinephrine should be available immediately to treat any acute hypersensitivity reaction.

Hypervolemia/Hemodilution
Hypervolemia may occur if the dosage and rate of infusion are not adjusted to the patient's volume status. At the first clinical signs of possible cardiovascular overload, e.g., headache, dyspnea, increased blood pressure, jugular venous distention, elevated central venous pressure, pulmonary edema, the infusion should be stopped immediately and the patient reevaluated. Albumin should be used with caution in conditions where hypervolemia and its consequences or hemodilution could represent a special risk for the patient.

Examples of such conditions are:
- Hypertension
- Esophageal varices
- Pulmonary edema
- Hemorrhagic diathesis
- Severe anemia
- Renal and post-renal anuria

Electrolyte Imbalance
When albumin is given, monitor the electrolyte status of the patient and take appropriate steps to restore or maintain the electrolyte balance.

Coagulation Abnormalities
If comparatively large volumes are to be replaced, monitoring of coagulation and hematocrit is necessary. Ensure adequate substitution of other blood constituents (coagulation factors, electrolytes, platelets and erythrocytes).

Laboratory Monitoring
If Albumin is to be administered, monitor hemodynamic performance regularly; this may include:
- Arterial blood pressure and pulse rate
- Central venous pressure
- Pulmonary artery occlusion pressure
- Urine output
- Electrolytes
- Hematocrit/hemoglobin.

Infection Risk from Human Plasma
This product is a derivative of human plasma. 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.

Special Population
Pregnancy
Animal reproduction studies have not been conducted with Human Normal Albumin 20% and 5% solution. It is not known whether Human Normal Albumin 20% and 5% solution can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity.

Albumin solution should be given to a pregnant woman only if clearly needed.

Nursing Mothers
It is not known whether this drug is excreted in human milk. Human Normal Albumin 20% and 5% should be given to nursing mothers only if necessary. Because many drugs are excreted in human milk, caution should be exercised when Human Normal Albumin 20% and 5% is administered to a lactating woman

Pediatric Use
The use of Human Normal Albumin 20% and 5% solution in children has not been associated with any special or specific hazard, if the dose is appropriate for the child's body weight. Data on the use of Human Normal Albumin 20% and 5% in children including premature babies are very limited. The product should be

For the use only of a Registered Medical Practitioner or Hospital or Laboratory

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administered to paediatric patients only if needed.

Geriatric Use
Clinical studies did not include a sufficient number of subjects aged 65 years and older to determine whether they respond differently from younger subjects.

ADVERSE EFFECTS
Untoward reactions to Human Normal Albumin 20% and 5% solution 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.

DOSAGE AND ADMINISTRATION
General Recommendations
ALBUBET® (Human Normal Albumin IP 20%) Solution must be administered intravenously. This solution may be administered directly by intravenous route or combined with other isotonic solutions (e.g. 5% glucose or 0.9% sodium chloride. The addition of four volumes of normal saline or 5% glucose to 1 volume of ALBUBET® gives a solution which is approximately isotonic and isosmotic with citrated plasma. Albumin solutions should not be mixed with protein hydrolysates or solutions containing alcohol.

The concentration of the albumin preparation, dosage and the infusion rate should be adjusted to the patient's individual requirements. The dose required depends on the body weight of the patient, the severity of trauma or illness and on continuing fluid and protein losses. Measures of adequacy of circulating volume and not plasma albumin levels should be used to determine the dose required.
The daily dose should not exceed 2 g of Human Normal Albumin per kg of body weight

Recommended Dosages
ALBUBET® 5% is administered intravenously. The total dosage will vary with the individual.

Hypovolemia
ALBUBET® 5%, dosage must be individualized, the initial dose should be 250 to 500 mL for older children and adults and 12 to 20 mL per kilogram of body weight for infants and young children. It may be repeated after 30 minute intervals if the response is not adequate.

Hypoalbuminemia
Daily dose should not exceed 2 g of albumin per kilogram of body weight.

Burns
ALBUBET® 5% is administered after the first 24 hours following burns, an initial dose of 500 mL is recommended.

Hemodialysis
Although not part of the regular regimen of renal dialysis it may be of value in patients with significant fluid overload prior to dialysis who may benefit from the administration of 100 to 200 mL human normal albumin at the end of the dialysis procedure.

Recommended Dosages
Dosage and Administration
Human Normal 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.
- The initial dosage in children will vary with the clinical state and body weight. A dose one-quarter to one-half the adult dose may be administered, or dosage may be calculated on the basis of 1-3 mL per kg of body weight.
- For infants suffering from hemolytic disease of the newborn the appropriate dose for binding of free serum bilirubin to albumin is 1 gram per kilogram of body weight. This may be administered before or during the exchange procedures.

In the treatment of the patient in shock with greatly reduced blood volume, Human Normal Albumin 20% and 5% may be administered as rapidly as necessary in order to improve the clinical condition and restore normal blood volume. This may be repeated in 15 - 30 minutes if the initial dose fails to prove adequate. In the patient with a slightly low or normal blood volume, the rate of administration should be 1 mL per minute. The usual rate of administration in children should be one-quarter the adult rate.

Preparation for Administration
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.

Administration
- Intravenous use only.
- Prior to administration, parenteral drug products should be inspected visually for turbidity and discoloration, whenever solution and container permit.
- Do not dilute with sterile water for injection.
- Do not use solutions of Human Normal Albumin 20% and 5% which are cloudy or have deposits. Once the infusion container has been opened the contents should be used immediately. Discard the unused portion.
  Filtration of Human Normal Albumin 20% and 5% is not required.
- The infusion rate should be adjusted according to the individual circumstances and the indication.
- The contents must not be used more than 4 hours after the container has been penetrated and any remnant portion must be discarded

Presentation
ALBUBET® & ALBUBET® 5% is available as an intravenous infusion in 100 mL vial in a carton.

Storage
Store between 2°C and 25°C in carton. Do not freeze. Protect from light.
Keep out of reach of children

Shelf Life: Please refer to carton/label.

Special precautions for disposal and other handling
Albumin solutions must not be diluted with water for injections as this may cause haemolysis in recipients.
Any unused medicinal product or waste material should be disposed off in accordance with local regulatory requirements.

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Electronics City, Phase - II,
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To report adverse events and/or product complaints visit our website **www.biocon.com** or call toll free No.: **1800 102 9465** or e mail us at **drugsafety@biocon.com**

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