Biocon

Human Albumin Solution Ph.Eur (20%)

ALBUBET® Safe-20% एलबुबेट सेफ़-२०%

Composition:
1 vial of 100ml contains
Human Albumin Solution Ph.Eur.....20g
Sodium caprylate (as stabilizer).....0.2659g
N-acetyl tryptophan Ph.Eur.....0.3940g
(as stabilizer)
Water for injection Ph.Eur.....q.s.

DESCRIPTION
ALBUBET®Safe-20%, Solution is a sterile, nonpyrogenic preparation of albumin in a single dosage form for intravenous administration. Each 100 mL contains 20 g of albumin and is prepared from human venous plasma using the Cohn cold ethanol fractionation process. After purification, stabilization and passage twice through a sterilizing filter, it is heated to 60°C for 10 hours. This treatment completely destroys the causative agents such as Hepatitis B Virus(HBV), Hepatitis C Virus (HCV) Human Immunodeficiency Virus(HIV) and so on.

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, HIV I & II antibodies and HCV RNA 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. Albumin 20% 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®Safe-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.)

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, ALBUBET®Safe-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.

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.

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 entered 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®Safe-20%. 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 ALBUBET®Safe-20% 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 Albumin 20% Solution. It is not known whether Albumin (Human) 20% Solution can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity.

Biocon

Human Albumin Solution Ph.Eur (20%)

ALBUBET® Safe-20% एलबुबेट सेफ़-२०%

ALBUBET®Safe-20%, 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. Albumin (Human) 20% should be given to nursing mothers only if necessary. Because many drugs are excreted in human milk, caution should be exercised when Albumin (Human) 20% is administered to a lactating woman

Pediatric Use
The use of Albumin (Human) 20% Solution in children has not been associated with any special or specific hazard, if the dose is appropriate for the child's body weight.

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

ADVERSE EFFECTS
Untoward reactions to Albumin (Human) 20% 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®Safe-20% (Human serum albumin) Solution must be administered intravenously. This solution may be administered in conjunction with or combined with other parenterals such as whole blood, plasma, saline, glucose or sodium lactate. The addition of four volumes of normal saline or 5% glucose to 1 volume of ALBUBET®Safe-20% 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 2g of Albumin (Human) 20% per kg of body weight

Recommended Dosages
Dosage and Administration
Albumin (Human) 20% is administered intravenously. The total dosage will vary with the individual.

- In adults, an initial infusion of 100mL 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 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, ALBUMIN 20% 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 Albumin (Human) 20% 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 Albumin (Human) 20% is not required.
- The infusion rate should be adjusted according to the individual circumstances and the indication.

Presentation
ALBUBET®Safe-20% is available as intravenous infusion in 100ml vial in a carton.

Storage
Store at temperature not exceeding 30°C (86°F). Do not freeze. Protect from light. Keep out of reach of children.

Shelf Life
36 months from the date of manufacturing.

For further details, please contact:
Medical Advisor
Biocon Limited
20th KM, Hosur Road, Electronics City,
Bangalore - 560 100. India

Manufactured by:
GREEN CROSS
320-2 Songdae-Ri, Ochang-Eup,
Chungwon-Kun, Chung CheongBuk-Do,
Korea.

Imported and Marketed by:
Biocon Limited
Konnar Industries, 29/A, 1st floor,
Veerasandra Industrial Area,
Electronics city, Bangalore - 560100. India.
® - Registered Trade Mark of Biocon Limited

Regd. office:
Biocon Limited
20th KM, Hosur Road, Electronics City,
Bangalore - 560 100. India.

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

BF/LL/0017/03

Ins-75-161-2