

AlbuRel Pack Insert

Size: 223 mm x 116 mm (Front & Back)

Front Side

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

HUMAN NORMAL ALBUMIN I.P.

*AlbuRel*TM

*AlbuRel*TM is available in 5% and 20% concentrations. Physicians are requested to refer to the contents chart for each formulation.

COMPOSITION

Each bottle contains:

Concentrations available (%)	20%	5%
Pack size	50ml/100ml	50ml/100ml
Total Protein	200 g/l	50 g/l
Sodium Caprylate	6.65 g/l	1.66 g/l
Na ⁺ not more than	160 mmol/l	160 mmol/l
K ⁺ not more than	2 mmol/l	2 mmol/l
Aluminium	200 µg/l	200 µg/l

*AlbuRel*TM does not contain any antimicrobial agents

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 by four times the volume infused. This extra fluid reduces haemoconcentration 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 haemodilution lasts for a shorter time when albumin is administered to individuals with normal blood volume. Albumin also functions as a transport protein and binds to naturally occurring, therapeutic and toxic materials in the circulation. The binding properties of albumin may, in special circumstances, provide an indication for its clinical use.

Albumin is distributed throughout the extracellular water and more than 60% of the body albumin pool is located in the extravascular fluid compartment. The total body albumin in a 70 Kg man is approximately 320 g; it has a circulating life span of 15-20 days, with a turnover of approximately 15 g per day.

CLINICAL INDICATIONS

Albumin (Human Albumin), may be given intravenously without dilution or it may be diluted with normal saline or 5% glucose before administration. The addition of one volume of albumin solution to four volumes of normal saline or 5% glucose gives a solution approximately isotonic and iso-osmotic with citrated plasma. When undiluted albumin solution is administered in patients with normal blood volume, the rate of infusion should be slow enough (1 ml per minute) to prevent too rapid expansion of plasma volume.

- I. **Hypo-volaemic shock:** Albumin is indicated in the treatment of hypo-volaemic shock associated with blood loss, trauma and surgical procedures. Albumin solutions are an accepted form of resuscitation, although crystalloids are the initial fluid of choice.
- II. **Burns:** Albumin is used for severe burns (>15% body surface area) after the first 24 hours, if hypo-proteinaemia develops and/or to maintain plasma volume.
- III. **Hypo-proteinemia:** Albumin is indicated in the treatment of hypo-proteinemia caused by a loss of plasma proteins. Loss of plasma proteins may occur through decreased absorption in gastrointestinal disorders, inadequate synthesis in chronic liver diseases or excessive urinary catabolism in chronic liver diseases. This loss of proteins leads to oedema, secondary to a fluid shift from the intravascular space to the interstitium and a compensatory increase in salt and water retention. Albumin serves to restore colloid osmotic pressure and in, conjunction with a diuretic, promotes diuresis.
- IV. **Ascites:** Albumin may be used to maintain cardiovascular function following removal of large volumes of ascitic fluid in patients suffering from ascites.
- V. **Plasma exchange/dialysis:** Albumin 20% may be used as an adjunct in patients who are undergoing long-term haemo-dialysis and are susceptible to shock and hypo-tension, or in dialysis patients who are hypo-volaemic and may not tolerate large volumes of crystalloid infusion as treatment for shock or hypo-tension.

PRODUCT SAFETY

The manufacturing process for *AlbuRel*TM uses plasma collected from approved blood banks where the donors are screened for their history as per guidelines laid down by the regulatory authorities. Their blood is screened for the mandatory infectious diseases. These are repeat donors whose samples are quarantined and retested. Only on being declared negative to HbsAg, HIV I & II antibodies and HCV RNA the plasma is used for processing.

The manufacturing procedure incorporates Heat Pasteurization (60°C for 10 hours), which inactivates viruses. After manufacturing, the product is tested by suitable methods to show freedom from viruses like HIV, HBV, HCV, Parvovirus and HAV. Multiple steps have been employed to assure product safety hence there is a very remote probability that unknown infectious agents may be present in these products like newer emerging viruses and theoretical CJD (Creutzfeldt Jakob disease). The process parameters, characterisations and final product quality are designed such, that they meet the regulatory requirements. Records of blood donors whose plasma have been used for manufacturing of this product has been maintained for at least ten years at the site of origin.

DOSAGE AND DIRECTIONS FOR USE

Albumin solutions need not be given through a filter. No compatibility testing (cross-matching) need to be performed since no ABO blood group antibodies are present.

Albumin 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 albumin administered ultimately must be guided by the haemodynamic response of the patient and the clinical indication for which it has been prescribed.

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Transfusions of whole blood or packed red blood cells may be necessary following administration of large volumes of albumin to restore the haemoglobin concentration and prevent anaemia.

Dosage guidelines:

The following dosages are included as a guideline only. The clinician should determine appropriate therapy after clinical assessment of the patient. Serum albumin values alone should not be used to determine dosage.

Hypovolaemia:

Adult dosage:

Start with 20 g of infusion and look for clinical response. May be repeated if necessary

Paediatric dosage:

Start with 0.5 to 1 g per Kg body weight and repeat if clinical response is not adequate

Burns:

Adult and Paediatric dosage:

Start with 20 g of Albumin, ensure adequate Plasma volume and repeat a similar dose after 24 hours

Hypoproteinaemia:

Two / three infusions of 20 g may be given with monitoring of protein levels.

Ascites:

Preferable to use 20 g to start with, but requires protein and fluid monitoring.

Plasma exchange and Dialysis:

25 g as an intravenous infusion not exceeding 30 ml / min during plasma exchange

OVERDOSAGE:

Rapid infusion and large volumes may cause hypervolaemia. The physician is recommended to look for clinical signs and symptoms and stop infusion immediately.

SIDE EFFECTS:

Allergic or pyrogenic reactions are characterized primarily by fever and chills. Rash, nausea, vomiting, tachycardia, hypo-tension and increased salivation have also been reported. Should an adverse reaction occur, stop the infusion immediately for a 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.

WARNINGS AND PRECAUTIONS

General :

Solutions of ALBUMIN (*AlbuRel*[™]) should not be used if they appear turbid or if there is sediment in the bottle. Contents must not be used more than four hours after the container has been penetrated. Discard unused portion.

Medical products prepared from human plasma carry a very remote risk of transmission of infective agents that are reduced by several methodologies.

Albumin should be administered with caution to patients with low cardiac reserve.

Rapid infusion may cause vascular overload with resultant pulmonary edema. Patients should be closely monitored for signs of increased venous pressure.

Patients with marked dehydration require administration of additional fluids. Albumin may be administered with the usual dextrose and saline intravenous solutions. However, solutions containing protein hydrolysates or alcohol must never be infused through the same administration set in conjunction with *AlbuRel*[™] since these combinations may cause precipitation of proteins.

Pregnancy Category C:

There are no known adverse reports on Albumin usage in pregnant women in any trimester or to the foetus.

Paediatric Use:

Appropriate dose based on body weight is not known to cause any undesirable effect.

CONTRAINDICATIONS

Albumin is contraindicated in patients with severe anaemia or cardiac failure in the presence of normal or increased intravascular volume.

The use of Albumin is contraindicated in patients with a history of allergic reactions to Albumin preparations.

PRESENTATION

AlbuRel[™] is available as 20% intravenous infusion in two packs, containing 20 g and 10 g of Human Albumin per 100 ml and 50ml respectively.

AlbuRel[™] is also available as 5% intravenous infusion in two packs, containing 5 g and 2.5 g of Human Albumin per 100ml and 50ml solution.

STORAGE

Store the container at or below 25°C. Do not freeze. Protect from light. Keep out of reach of children.

SHELF LIFE

3 years from the date of manufacturing.



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