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

# Human Albumin Solution BP 20 %

# Vi-Alb

Vi-Alb is available in 5% and 20% concentration. Physicians are requested to refer to the contents chart for composition.

**COMPOSITION:**
Each Vial contains:

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|---|---|
| Concentration Available (%) | 5% |
| Pack Size | 50 mL /100 mL |
| 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 |

| | |
|---|---|
| Concentration available (%) | 20% |
| Pack Size | 10mL/20mL/50mL/100 mL |
| 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 |

Vi-Alb does not contain any antimicrobial agents

**CLINICAL PHARMACOLOGY:**
Albumin is a highly soluble, globular protein (Molecular weight 66,500 Daltons), accounting for 70-80% of the colloid osmotic pressure of plasma. 20 % albumin solution increases the circulating plasma volume by four times the volume infused, leading to reduced haemoconcentration and blood viscosity. The extent and duration of volume expansion depend upon the initial blood volume. The effect of albumin infusion may persist for many hours in patients with decreased blood volume. Albumin binds to several naturally occurring, therapeutic and toxic materials in the circulation and also acts as a transport protein. These binding properties may provide an indication for its clinical use under special circumstances.

**INDICATIONS:**
Vi-Alb (Human Albumin) may be given intravenously with or without dilution (normal saline or 5 % glucose). A 4-times dilution gives a solution approximately isotonic and iso-osmotic with citrated plasma.

1. Hypovolaemic shock: Vi-Alb is indicated in the treatment of hypovalaemic shock associate with blood loss, trauma and surgical procedures.
2. Burns: Vi-Alb is used for severe burns (>15% body surface area) after the first 24 hours, If hypoproteinaemia develops and / or to maintain Plasma volume.
3. Hypoproteinaemia caused by a loss of plasma proteins.
4. Ascites: Vi-Alb may be used to maintain cardiovascular function following removal of large volumes of ascetic fluid in patients suffering from ascites.
5. Plasma Exchange/dialysis: Vi-Alb may be used as an adjunct in patients who are undergoing long term haemodialysis and are suspceptible to shock and hypotension or in dialysis patients who are hypovolaemic and may not tolerate large volumes of crystalloid infusion as treatment for shock or hypotension.

**PRODUCT SAFETY:**
Plasma collected from approved blood banks is used for manufacture of Vi-Alb. After screening the donors for their disease history as per regulatory guidelines, the blood is collected and screened for mandatory infectious disease. The plasma is used for processing only after it is declared negative to HbsAg, HIV I & II antibodies and HCV RNA. As these are repeat donors their samples are quarantined and retested.
The heat Pasteurization (60°C for 10 hours) is used during product manufacture to inactivate viruses. The final product is tested by suitable methods to show freedom from viruses like HIV, HBV, HCV, Parvovirus and HAV. Product Safety is assured through multiple safety measures. Hence there is a very remote probability for the presence of unknown infectious agents like newly emerging viruses and theoretical CJD (Creutzfeldt Jakob Disease). The process parameters, characterizations and final product quality meet the regulatory requirements. Records of blood donors whose plasma has been used for manufacturing of Albumin is being maintained for at least ten years at the site of origin.

**DOSAGE AND DIRECTIONS FOR USE:**
Albumin solution need not be given through a filter. As ABO blood group antibodies are absent, compatibility testing (cross testing) is not required.
Being a hyper osmotic, albumin should be given by slow intravenous infusion at a rate of about 1 mL/minute. Ultimately, the total volume of albumin to be administered and rate of infusion must be guided by the haemodynamic response of the patient and the clinical condition for which it has been prescribed.
To restore the haemoglobin concentrations and prevent anaemia, transfusion of whole blood or packed red blood cells may be required following the administration of large volumes of albumin.

**OVERDOSAGE:**
Rapid infusion and large volumes may cause hypervolaemia. The physician is recommended to look for clinical signs and symptoms of hypervolaemia and if present, infusion should be immediately stopped.

**SIDE EFFECTS:**
Allergic or pyrogenic reactions are characterized primarily by fever and chills. Rash, nausea, vomiting tachycardia, hypo-tension and increased salivation have been reported. In case of an adverse reaction, stop the infusion immediately for a period of time, which may result in the disappearance of the symptoms. If administration is stopped and the patient requires additional albumin, material from a different batch should be used. Rapid administration of albumin may result in vascular overload with resultant pulmonary edema.

**WARNINGS AND PRECAUTIONS:**
**General:**
- Solution of albumin (Vi-Alb) should not be used if it appears turbid or if there is any sediment in the bottle. Contents must not be used beyond four hours after the container has been penetrated. Discard unused portions.
- There is a very remote risk of transmission of infective agents.
- Albumin should be administered with caution to patients with low cardiac reserve.
- Rapid infusion of albumin may cause vascular overload with resultant pulmonary edema. Patients should be closely monitored for signs of increases venous pressure.
- Administration of additional fluids is required for patients with marked dehydration.
- 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 infusion set in conjunction with Vi-Alb since these combinations may cause precipitation of proteins.

**Pregnancy Category C:**
There are no known adverse reports on albumin usage in pregnant women. It should be used in pregnant women only when potential benefits outweighs the risk to foetus.

**Pediatric use:**
Appropriate dose based on body weight is not known to cause any undesirable effect.

**PRESENTATION:**
5% Vi-Alb is available in 50 mL and 100 mL Pack size
20% Vi-Alb is available 10 mL, 20 mL , 50 mL and 100 mL of Pack size.

**STORAGE:**
Store the container at or below 25°C. Do not freeze. Protect from light.

**Keep out of reach and sight of children.**

**Manufactured by:**
Virchow Biotech Pvt. Ltd.,
Survey No.172 Part, Gagillapur, Dundigal-Gandimaisamma (M),
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