Human Albumin Solution I.P. 5%, 20% & 25%

ABBREVIATED PRESCRIBING INFORMATION

Before prescribing and for complete details please consult the India Package Insert.

Active Ingredient: Human Albumin Solution 25% is a solution containing 250 g/l of total protein of which at least 95% is human albumin. A vial of 50 ml contains 12.5 g of human albumin. A vial of 100 ml contains 25 g of human albumin.

Human Albumin Solution 20% is a solution containing 200 g/l of total protein of which at least 95% is human albumin. A vial of 50 ml contains 10 g of human albumin. A vial of 100 ml contains 20 g of human albumin.

Human Albumin Solution 5% is a solution containing 50 g/l of total protein of which at least 95% is human albumin. A vial of 250 ml contains 12.5 g of human albumin. A vial of 500 ml contains 25 g of human albumin

Dosage form: Solution for infusion. A clear, slightly viscous liquid; it is almost colorless, yellow, amber, or green.

Therapeutic Indications: Restoration and maintenance of circulating blood volume where volume deficiency has been demonstrated and use of a colloid is appropriate. The choice of albumin rather than artificial colloid will depend on the clinical situation of the individual patient, based on official recommendations.

Dosage and Administration: 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 patient's body weight, severity of injury/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. If human albumin is to be administered, hemodynamic performance should be monitored regularly; this may include: arterial blood pressure and pulse rate, central venous pressure, pulmonary artery wedge pressure (PCW-pressure), urine output, electrolyte, hematocrit/ hemoglobin, clinical signs of cardiac/respiratory failure (e.g. dyspnoea), clinical signs of increasing intra-cranial pressure (e.g. headache).

Human Albumin Solution 25% or 20% or 5% can be directly administered by the intravenous route, or it can also be diluted in an isotonic solution (e.g. 5 % glucose or 0.9 % sodium chloride). The infusion rate should be adjusted according to the individual circumstances and the indication. In plasma exchange the infusion rate should be adjusted to the rate of removal. Albumin solutions must not be diluted with water for injections as this may cause haemolysis in recipients. If large volumes are administered, the product should be warmed to room or body temperature before use. Do not use solutions which are cloudy or have deposits. This may indicate that the protein is unstable or that the solution has become contaminated. Do not use unless seal is intact. If leaks are found, discard. Once the container has been opened, the contents should be used immediately. The contents must not be used more than 4 hours after the container has been penetrated and any remnant portion must be discarded. Do not use after expiry.

Contraindications: Patients with a history of Hypersensitivity reaction to albumin preparations or to any of the excipients (sodium-acetyltryptophan and sodium caprylate).

Special Warnings and precautions for use

Suspicion of allergic or anaphylactic type reactions requires immediate discontinuation of the infusion. In case of shock, standard medical treatment for shock should be implemented. Albumin should be used with caution in conditions where hypervolaemia and its consequences or haemodilution could represent a special risk for the patient. Examples of such conditions are: Decompensated cardiac insufficiency, Hypertension, Oesophageal varices, Pulmonary oedema, Haemorrhagic diathesis, Severe anaemia, Renal and post-renal anuria. The colloid-osmotic effect of Human Albumin Solution 25% is approximately four times that of blood plasma. Therefore, when concentrated albumin is administered, care must be taken to assure adequate hydration of the patient. Patients should be monitored carefully to guard against circulatory overload and hyperhydration. 200-250 g/l human albumin solutions are relatively low in electrolytes compared to the 40 – 50 g/l human albumin solutions. When albumin is given, the electrolyte status of the patient should be monitored, and appropriate steps taken to restore or maintain the electrolyte balance. Albumin solutions must not be diluted with water for injections as this may cause haemolysis in recipients. Hypervolaemia may occur if the dosage and rate of infusion are not adjusted to the patient's circulatory situation. Standard measures to prevent infections resulting from the use of medicinal products prepared from human blood or plasma include selection of donors, screening of individual donations and plasma pools for specific markers of infection and the inclusion of effective manufacturing steps for the inactivation/removal of viruses. Despite this, when medicinal products prepared from human blood or plasma are administered, the possibility of transmitting infective agents cannot be totally excluded. This also applies to unknown or emerging viruses and other pathogens. There are no reports of virus transmissions with albumin manufactured to European Pharmacopoeia specifications by established processes. It is strongly recommended that every time that Human Albumin is administered to a patient, the name and batch number of the product are recorded in order to improve the traceability of biological medicinal products and maintain a link between the patient and the batch of the product.

Warning: For the use of registered medical practitioner or hospital or laboratory only

Pregnancy, Lactation, Pediatric and Geriatric Use: The safety of Human Albumin Solution 25% or 20% or 5% for use in human pregnancy has not been established in controlled clinical trials. However, clinical experience with albumin suggests that no harmful effects on the course of pregnancy, or on the foetus and the neonate are to be expected. The effects of human albumin on fertility have not been established in controlled clinical trials. No animal reproduction studies have been conducted with Human Albumin Solution. Experimental animal studies are insufficient to assess the safety with respect to reproduction, development of the embryo or foetus, the course of gestation and peri-and postnatal development. However, human albumin is a normal constituent of human blood.

Adverse Reactions: In cases of severe reactions, the infusion should be stopped and an appropriate treatment should be initiated. In post-marketing surveillance the following adverse events have been reported. These events are listed by MedDRA System Organ Class, then by Preferred Term in order of severity. Immune System Disorders: Anaphylactic shock, anaphylactic reaction, hypersensitivity/allergic reactions; Nervous System Disorders: Headache, dysgeusia; Cardiac Disorders: Myocardial infarction, atrial fibrillation, tachycardia; Vascular Disorders:

Hypotension, flushing; Respiratory, Thoracic, and Mediastinal Disorders: Pulmonary edema, dyspnea; Gastrointestinal Disorders: Vomiting, nausea; Skin and Subcutaneous Tissue Disorders: Urticaria, rash, pruritus; General Disorders and Administration Site Conditions: Chills. There are no data available on adverse reactions from company-sponsored clinical trials conducted with Albumin (Human).

Overdose - Hypervolemia may occur if the dosage and rate of infusion are too high.

Shelf Life: 36 months

Storage: Store at room temperature not to exceed 25°C. Do not freeze.

Imported and Marketed by: Takeda Biopharmaceuticals India Pvt. Ltd., Khasra No. 1/24, 25, 3/1/1, Gala No. 1A-1F, 2A-2E, 3B-3E and 4A-4E, Warehouse No. 1, Sector-76, Hasanpur Darbaripur, Gurugram - 122004, Haryana, India

Before prescribing, consult full prescribing information. Full prescribing information is available on request.

Suspected Adverse Events should be reported to Takeda at: AE.India@takeda.com

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