Albumin (Human) Solution I.P. 20% & 25%

FLEXBUMIN® 20% & 25%

ABBREVIATED PRESCRIBING INFORMATION

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

Active Ingredient: Human Albumin Solution IP 20% and 25% in 50ml and 100ml presentation

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

FLEXBUMIN® 20% is a solution containing 10 g of albumin per 50 mL and 20 g of albumin per 100 mL respectively.

FLEXBUMIN® 25% is a solution containing 12.5 g of albumin per 50 mL and 25 g of albumin per 100 mL respectively.

Therapeutic Indication: 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: For intravenous use only. 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).

Visually inspect parenteral drug product for particulate matter and discoloration prior to administration. FLEXBUMIN® is a transparent or slightly opalescent solution, which may have a greenish tint or may vary from a pale straw to an amber color. Do not use unless solution is clear of particulate matter or if the solution is turbid. Check the container for minute leaks prior to use by squeezing the bag firmly. If leaks are found, discard solution. Do not use the bag if the tip protector is damaged, detached or missing. Do not dilute with Sterile Water for Injection. Acceptable diluents include 0.9% Sodium Chloride or 5% Dextrose in Water. Do not mix or add with other medicinal products including blood and blood components, protein hydrolysates or solutions containing alcohol. Do not add supplementary medication. The contents must not be used more than 4 hours after the container is penetrated and any remnant portion must be discarded. Monitor hemodynamic parameters in patients receiving FLEXBUMIN® and check for the risk of hypervolemia and cardiovascular overload. Record the name and batch number of the product to maintain a link between the patient and the product. Discard unused portion.

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

anaphylactic shock, anaphylactic reaction, or hypersensitivity/allergic reactions. Patients with severe anemia or cardiac failure with normal or increased intravascular volume.

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 200 g/l or 250 g/l 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. Flexbumin® 20% and 25% 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. If comparatively large volumes are to be replaced, controls of coagulation and haematocrit are necessary. Care must be taken to ensure adequate substitution of other blood constituents (coagulation factors, electrolytes, platelets and erythrocytes). 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 Flexbumin® is administered to a patient, the name and batch number of the product are recorded in order to maintain a link between the patient and the batch of the product.

Pregnancy and lactation: No human or animal data are available to indicate the presence or absence of drug-associated risk. It is not known whether Flexbumin® can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. It is not known whether Flexbumin® is excreted in human milk.

Pediatric and Geriatric Use: The safety of albumin solutions has been demonstrated in children provided the dose is appropriate for body weight; however, the safety of Flexbumin® has not been evaluated in sponsor conducted pediatric studies. Geriatric Use: No human or animal data.

Adverse Reactions The most serious adverse reactions are hypersensitivity reaction (including anaphylactic reaction) and pulmonary edema. No sponsor initiated clinical studies have been conducted with Flexbumin®. The following adverse reactions have been reported in the post approval use of Flexbumin®- 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: Pyrexia, chills. Healthcare professionals are asked to report any suspected adverse reactions to the Manufacturer/Importer and via the national reporting system. The physician should discuss the risks and benefits of this product with the patient.

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.

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

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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