

FLEXBUMIN 25% [Albumin (Human)]

Indication

FLEXBUMIN 25% is a sterile, nonpyrogenic preparation of albumin in a single dosage form for intravenous administration. FLEXBUMIN 25% is indicated in hypovolemia, hypoalbuminemia due to inadequate production, excessive catabolism, hemorrhage, major surgery or burns, and for use during cardiopulmonary bypass surgery.

Important Risk Information for FLEXBUMIN 25%

FLEXBUMIN 25% is contraindicated in patients with cardiac failure, in patients with severe anemia and in patients with a history of allergic reactions to human albumin.

Do not use if turbid. Do not begin administration more than 4 hours after the container has been entered.

Do not use Sterile Water for Injection as a diluent. 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 FLEXBUMIN 25%. Acceptable diluents include 0.9% Sodium Chloride or 5% Dextrose in Water.

FLEXBUMIN 25% is made from pooled human plasma. It may carry a risk of transmitting infectious agents, e.g., viruses and theoretically, the Creutzfeldt–Jakob disease (CJD) agent.

FLEXBUMIN 25% must be administered intravenously at a rate not to exceed 1ml/min to patients with normal blood volume, due to the risk of developing circulatory overload and pulmonary edema.

When 25% albumin is infused, a rise in blood pressure necessitates careful observation to detect and treat severed blood vessels that may not have bled at a lower blood pressure.

Adverse reactions to FLEXBUMIN 25% are extremely rare, although nausea, fever, chills or urticaria may occasionally occur.

CAUTION: Do not use plastic containers in series connections. Such use could result in air embolism due to residual air being drawn from the primary container before the administration of the fluid from the secondary container is complete.

Please see Preparation for Administration for FLEXBUMIN 25% in the Prescribing Information.

Please refer to page () for more detailed risk information. Please see accompanying FLEXBUMIN 25% Prescribing Information for full prescribing details.