

Important Safety Information

Albumin (Human) 25%

CONTRAINDICATIONS

Hypersensitivity to albumin preparations or to any of the excipients.

Albumin should be used with caution in conditions where hypervolemia and its consequences or hemodilution could represent a special risk for the patient.

Examples of such conditions are:

- Decompensated cardiac insufficiency
- Hypertension
- Esophageal varices
- Pulmonary edema
- Hemorrhagic diathesis
- Severe anemia
- Renal and post-renal anuria

WARNINGS

Albumin (Human) 25% is made from human plasma. Products made from human plasma may contain infectious agents, such as viruses, that can cause disease. The risk that such products will transmit an infectious agent has been reduced by screening plasma donors for prior exposure to certain viruses, by testing for the presence of certain current virus infections, and by inactivating certain viruses by pasteurization. Despite these measures, such products can still potentially transmit disease. A theoretical risk for transmission of Creutzfeldt-Jakob disease (CJD) also is considered extremely remote. No cases of transmission of viral diseases or CJD have ever been identified for albumin. There is also the possibility that unknown infectious agents may be present in such products. ALL infections thought by a physician possibly to have been transmitted by this product should be reported by the physician or other healthcare provider to Octapharma, at 866-766-4860. The physician should discuss the risks and benefits of this product with the patient.

Do not use solutions of Albumin (Human) 25% which are cloudy or have deposits. Once the infusion container has been opened the content should be used immediately. Discard unused portion.

Albumin solutions must not be diluted with water for injections as this may cause hemolysis in recipients.

PRECAUTIONS

20-25% human albumin solutions are relatively low in electrolytes compared to the

4-5% 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.

If comparatively large volumes are to be replaced, controls of coagulation and hematocrit are necessary. Care must be taken to ensure adequate substitution of other blood constituents (coagulation factors, electrolytes, platelets and erythrocytes).

Hypervolemia may occur if the dosage and rate of infusion are not adjusted to the patient's circulatory situation. At the first clinical signs of cardiovascular overload (headache, dyspnea, jugular vein congestion), or increased blood pressure, raised venous pressure and pulmonary edema, the infusion is to be stopped immediately. [8]

Pregnancy Category C

Animal reproduction studies have not been performed with Albumin (Human) 25%. It is also not known whether Albumin (Human) 25% can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Albumin (Human) 25% should be given to a pregnant woman only if clearly needed.

ADVERSE REACTIONS

Adverse reactions for Albumin (Human) 25% are rare. These reactions normally disappear rapidly when the infusion rate is slowed down or the infusion is stopped. In case of severe reactions, the infusion should be stopped and an appropriate treatment should be initiated.

Do not freeze.

Do not use after expiration date.