

Kamapharm Albumin (Human) 20% or 25%

Albumin Human
(Normal Serum Albumin), U.S.P.
20% or 25% Solution

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Description

Kamapharm Albumin (Human) 20% or 25% solutions are sterile aqueous solutions for single dose intravenous administration containing 20% or 25% of human albumin (weight/volume). The products are stabilized with 0.08 millimoles sodium caprylate and 0.08 millimoles N-acetyl-DL-tryptophan per gram of protein. Kamapharm Albumin 20% solution is osmotically equivalent to four times its volume of normal citrated plasma, whereas the 25% solution is equivalent to five times its volume of normal citrated plasma. Kamapharm Albumin solution contains 130-160 milliequivalents of sodium ion per liter and has a pH of 6.9 ± 0.5 . The product contains no preservatives. Kamapharm Albumin (Human) is prepared from pooled human plasma obtained from venous blood.

Kamapharm Albumin (Human) is heat-treated for virus inactivation at 60°C for 10 hours. The product is produced from units of human plasma that have been tested and found non-reactive for hepatitis B surface antigen (HBsAg), and for antibody to Hepatitis C virus (anti-HCV) and HIV I/II by FDA- and/or EC- approved tests.

Administration and Dosage

Administered by IV infusion only.

Preparation: May be given undiluted or diluted in normal saline. If sodium restriction is required, administer either undiluted or diluted in a sodium-free carbohydrate solution such as 5% Dextrose in Water.

Because of the risk of potentially life threatening hemolysis, the dilution of human albumin with sterile water for injection should be avoided!

Indications

Unless the condition responsible for hypoproteinemia can be corrected, albumin in any form can provide only symptomatic relief of supportive treatment.

Shock:

In the emergency treatment of shock due to burns, trauma, surgery and infections. The initial dose should be determined by the patient's condition and response to treatment. Guide therapy by the degree of venous and pulmonary congestion, and hemoglobin or hematocrit measurement.

Greatly reduced blood volume: Administer as rapidly as desired. If the initial response is inadequate, additional albumin may be given 15 to 30 minutes following the first dose.

Slightly low or normal blood volume: The rate of administration should be 1 ml/minute. If there is continued loss of protein, it may be desirable to give whole blood or other blood fractions.

Hypoproteinemia:

For hypoproteinemia, as in nephrotic syndrome, hepatic cirrhosis and toxemia of pregnancy. Also in postoperative patients, tuberculosis patients and premature infants. These clinical situations are characterized by a low concentration of plasma protein and consequently, a reduced volume of circulating blood.

Hypoproteinemia with or without edema: Unless the underlying pathology responsible for the hypoproteinemia can be corrected, the IV administration of albumin 20% or 25% is purely symptomatic or supportive. The usual daily dose of albumin for adults is 50 to 75 g and for children is 25 g. Patients with severe hypoproteinemia who continue to lose albumin may require larger quantities. Since hypoproteinemic patients usually have approximately normal blood volumes, the rate of administration should not exceed 2.0 ml per minute, as more rapid injection may precipitate circulatory embarrassment and pulmonary edema.

Hepatic cirrhosis:

May be effective in temporarily restoring plasma levels in the absence of ascites. If ascites is present, albumin may be of value after the removal of a large fluid volume (e.g., more than 1500 ml during a

lot should be used. Albumin, particularly if administered rapidly, may result in vascular overload with resultant pulmonary edema.

Storage

Store at room temperature not exceeding 30°C. Protect from freezing. Kamapharm Albumin (Human) 20% or 25% are stable for three years.

Caution

This product may not be dispensed without a doctor's prescription.

Supplied

In vials of 50 ml or 100 ml. Each vial contains 20 % or 25% albumin (Human) solution.

For 20% Israel License No. 039032598800

For 25% Israel License No. 457826315

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Beit Kama, ISRAEL

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