Approved on: June 29, 2007

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Instructions for Human Albumin

Please read the instructions carefully and use the product under the guidance of a physician

WARNING: This product is a human blood product. Despite screening and viral inactivation, the potential risk of transmitting blood-borne diseases caused by viruses or other unknown pathogens cannot be completely eliminated.

[Drug Name]

Generic Name: Human Albumin

English Name: Human Albumin

Chinese Pinyin: Renxue Baidanbai

[Ingredients]

Human albumin. This product is made from healthy human plasma, with proteins separated and purified by cold ethanol fractionation, and with viruses inactivated by heating at 60 ℃ for 10 hours. It contains suitable sodium caprylate as a stabilizer and does not contain preservatives and antibiotics.

[Appearance]

This product is a slightly viscous, yellow or green to brown clear liquid and shall not be turbid.

[Indications]

1. Traumatic hemorrhagic shock and burn shock.
2. Increased intracranial pressure caused by cerebral edema and injury.
3. Edema or ascites caused by liver cirrhosis and nephrosis.
4. Prevention and treatment of hypoproteinemia.
5. Hyperbilirubinemia of newborn.
6. Heart-lung bypass, adjunctive therapy for burns, adjunctive therapy for hemodialysis and adult respiratory distress syndrome.

[Strength]

10 g/vial (20%, 50 ml)

[Usage and Dosage]

Usage: Generally administered via IVGTT or IV bolus. To prevent dehydration of tissues during large volume injections, 5% glucose injection or sodium chloride injection can be used for appropriate dilution for IVGTT (preferably with a blood

transfusion apparatus equipped with a filter). The infusion rate shall be kept at no more than 2 ml per minute, but particular attention shall be paid to a slow rate at the beginning for the first 15 minutes, gradually increasing to the aforementioned rate.

Dosage: The dosage shall be determined by the physician based on individual considerations. In general, for conditions such as severe burns or hemorrhagic shock, an initial injection of 5-10 g of the drug may be administered directly. This can be repeated every 4-6 hours with another injection. In the treatment of chronic conditions such as nephropathy and liver cirrhosis, with associated hypoalbuminemia, the drug can be administered at a dosage of 5-10 g per day. This regimen can be continued until edema subsides and serum albumin levels return to normal.

[Adverse Reactions]

The use of this product generally does not produce adverse reactions. Occasionally, symptoms such as chills, fever, flushing, rash, nausea, and vomiting may occur. Rapid infusion can lead to vascular overload and cause pulmonary edema, and allergic reactions may occur occasionally.

[Contraindications]

1. Patients with a severe allergy to albumin.

2. Patients with hypertension, acute heart disease, normal blood volume and high blood volume heart failure.

3. Patients with severe anemia.

4. Patients with renal insufficiency.

[Precautions]

1. The drug shall not be used if the liquid appears turbid, precipitated, or contaminated with foreign particles, or if the vial is cracked, the vial cap is loose, or the drug has expired.

2. After opening, this product shall be infused for one time and shall not be used several times or infused to another person.

3. If any adverse reactions are observed during the infusion process, it is important to stop the administration immediately.

4. Patients with significant dehydration shall also receive fluid replacement therapy concurrently.

5. It is strictly prohibited to freeze the product during transportation and storage.

[Use in Pregnant and Lactating Women]

Medication use in pregnant women or women who may become pregnant shall be approached with caution. If necessary, it shall be used under the guidance of a physician and with close monitoring.

[Pediatric Use]

Unknown

[Geriatric Use]

Unknown

[Drug Interactions]

This product shall not be mixed with vasoconstrictors, proteolytic enzymes, or injections containing alcohol solvents.

[Overdose]

Excessive administration of this product, due to its hypertonic effect, may lead to dehydration, increased systemic circulatory load, congestive heart failure, and pulmonary edema.

[Pharmacology and Toxicology]

Pharmacological action: 1. Increase of blood volume and maintenance of plasma colloid osmotic pressure; albumin accounts for 80% of the plasma colloid osmotic pressure and primarily regulates the dynamic balance of water between tissues and blood vessels. Due to its relatively high molecular weight, albumin diffuses slowly across membranes compared to salts and water. This characteristic allows albumin's colloid osmotic pressure to counterbalance the hydrostatic pressure of the capillaries, thereby maintaining normal and constant blood volume. Additionally, in the circulatory system, 1 g of albumin can retain approximately 18 ml of water, and the water-retaining capacity of 5 g of albumin is roughly equivalent to 100 ml of plasma or 200 ml of whole blood. This function contributes to increasing circulatory blood volume and maintaining plasma colloid osmotic pressure.

2. Transportation and detoxification: Albumin can bind both anions and cations, can transport different substances, and can also transport toxic substances to detoxification organs.

3. Nutritional supply: Tissue proteins and plasma proteins can convert to each other. When nitrogen metabolism is impaired, albumin can serve as a nitrogen source to provide nutrition for tissues.

Toxicological Studies: unknown.

[Pharmacokinetics]

Unknown

[Storage and Transportation]

This product shall be stored and transported at room temperature (10-30°C) in a light-protected manner. It can also be transported at 2-8°C.

[Packaging]

Medium borosilicate glass-molded injection vials with halogenated butyl rubber stopper (brominated) for injection. 1 vial/box.

[Shelf Life]

36 months

[Executive Standards]

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