BIOHUI®
博晖生物

Approved on: June 29, 2007
Revised on: November 05, 2012, January 18, 2019, December 30, 2020, and May 25, 2023

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
Human Albumin
English Name: Human Albumin
Renxue Baidanbai
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 following adverse reactions/events were reported for human albumin injections in post-marketing surveillance:

Systemic disorders and reactions at the administration site: fever, chills, chest discomfort, cold sensation, weakness, edema, pain, chest pain, and rash, swelling and pain at the injection site;
Skin and subcutaneous tissues: rash, urticaria, maculopapular rash, papules, erythema, blisters, pruritus, hyperhidrosis, skin swelling, purpura, angioedema;

Respiratory system, chest, and mediastinum: dyspnea, tachypnea, decreased oxygen saturation, cough, laryngeal edema, asthma, pulmonary edema;
Gastrointestinal system: nausea, vomiting, diarrhea, abdominal pain, bloating, abdominal discomfort, oral paresthesia, gastrointestinal bleeding;
Immune system: hypersensitivity, anaphylactoid reaction, severe immediate allergic reaction, anaphylactic shock;
Heart: palpitations, tachycardia, arrhythmia, atrial fibrillation, bradycardia, heart failure, myocardial infarction;
Nervous system: dizziness, headache, tremor, hypoesthesia, taste disorder, somnolence, coma, syncope, loss of consciousness;
Blood and lymphatic vessels: flushing, cyanosis, pallor, cold extremities, hypotension, hypertension, phlebitis;
Mental system: restlessness, convulsions, mental disorders, confusion, insomnia, agitation;
Hepatobiliary system: liver dysfunction;
Renal and urinary system: hematuria, oliguria, urinary incontinence, renal impairment;
Hematologic and lymphatic systems: hemolysis.
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 study: unknown.

[Pharmacokinetics]

Unknown

[Storage and Transportation]

Store and transport at room temperature (10-30°C) away from light, or transport 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]

Volume III of Chinese Pharmacopoeia (Edition 2025) and YBS00542012

[Approval No.]

GYZZ S20023010

[Marketing Authorization Holder]

Bohui Biopharmaceutical (Hebei) Co., Ltd.

[Manufacturer]

Name: Bohui Biopharmaceutical (Hebei) Co., Ltd.
Address: No. 6 of Qingshan Road, Luquan Lvdao Torch Development Zone, Shijiazhuang City
Postal Code: 050200
Tel: 0311-83935518