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# 人血白蛋白说明书

请仔细阅读说明书并在医师指导下使用

## 警 示

因原料来自人血，虽然对原料血浆进行了相关病原体的筛查，并在生产工艺中加入了去除和灭活病毒的措施，但理论上仍存在传播某些已知和未知病原体的潜在风险，临床使用时应权衡利弊。

【药品名称】	通用名称：人血白蛋白 英文名称：Human Albumin 汉语拼音：Ren Xue Baidanbai
【成份】	本品系由健康人血浆，经低温乙醇蛋白分离法分离纯化，并经60℃10小时加温灭活病毒后制成。含适宜稳定剂，不含防腐剂和抗生素。 本品使用的辅料：辛酸钠。
【性状】	本品应为略黏稠、黄色或绿色至棕色澄明液体，不应出现浑浊。
【适应症】	1. 失血创伤、烧伤引起的休克。 2. 脑水肿及损伤引起的颅压升高。 3. 肝硬化及肾病引起的水肿或腹水。 4. 低蛋白血症的防治。 5. 新生儿高胆红素血症。 6. 用于心肺分流术、烧伤的辅助治疗、血液透析的辅助治疗和成人呼吸窘迫综合征。
【规格】	5g(20%, 25ml)/瓶、10g(20%, 50ml)/瓶、10g(10%, 100ml)/瓶、5g(10%, 50ml)/瓶、2g(10%, 20ml)/瓶、12.5g(25%, 50ml)/瓶。
【用法用量】	用法：一般采用静脉滴注或静脉推注。为防止大量注射时机体组织脱水，可采用5%葡萄糖注射液或氯化钠注射液适当稀释作静脉滴注（宜用备有滤网装置的输血器）。滴注速度应以每分钟不超过2ml为宜，但在开始15分钟内，应特别注意速度缓慢，逐渐加速至上述速度。用量：使用剂量由医师酌情考虑，一般因严重烧伤或失血等所致休克，可直接注射本品5~10g，隔4~6小时重复注射1次。在治疗肾病及肝硬化等慢性白蛋白缺乏症时，可每日注射本品5~10g，直至水肿消失，血清白蛋白含量恢复正常为止。
【不良反应】	使用本品一般不会产生不良反应，偶可出现寒颤、发热、颜面潮红、皮疹、恶心呕吐等症状，快速输注可引起血管超负荷导致肺水肿，偶有过敏反应。
【禁忌】	1. 对白蛋白有严重过敏者。 2. 高血压患者，急性心脏病者、正常血容量及高血容量的心力衰竭患者。 3. 严重贫血患者。 4. 肾功能不全者。
【注意事项】	1. 药液呈现混浊、沉淀、异物或瓶子有裂纹、瓶盖松动、过期失效等情况不可使用。 2. 本品开启后，应一次输注完毕，不得分次或给第二人输用。 3. 输注过程中如发现病人有不适应反应，应立即停止输用。 4. 有明显脱水者应同时补液。 5. 运输及贮存过程中严禁冻结。
【孕妇及哺乳期妇女用药】	对孕妇或可能怀孕妇女的用药应慎重，如有必要应用时，应在医师指导和严密观察下使用。
【儿童用药】	尚不明确。
【老年用药】	尚不明确。
【药物相互作用】	本品不宜与血管收缩药、蛋白水解酶或含酒精溶剂的注射液混合使用。
【药物过量】	因本品有高渗作用，过量注射时，可造成脱水、机体循环负荷增加、充血性心力衰竭和肺水肿。
【药理毒理】	药理作用： 1. 增加血容量和维持血浆胶体渗透压：白蛋白占血浆胶体渗透压的80%，主要调节组织与血管之间水分的动态平衡。由于白蛋白分子量较高，与盐类及水分相比，透过膜内速度较慢，使白蛋白的胶体渗透压与毛细血管的静水压抗衡，以此维持正常与恒定的血容量；同时在血循环中，1g白蛋白可保留18ml水，每5g白蛋白保留循环内水分的能力约相当于100ml血浆或200ml全血的功能，从而起到增加循环血容量和维持血浆胶体渗透压的作用。 2. 运输及解毒：白蛋白能结合阴离子也能结合阳离子，可以输送不同的物质，也可以将有毒物质输送到解毒器官。 3. 营养供给：组织蛋白和血浆蛋白可互相转化，在氮代谢障碍时，白蛋白可作为氮源为组织提供营养。 毒理研究：尚不明确。
【药代动力学】	尚不明确。
【贮藏】	于2~30℃避光保存和运输。
【包装】	包装材料和容器：玻璃瓶；包装规格：1瓶/盒。
【有效期】	36个月。
【执行标准】	《中国药典》2020年版三部与[5g(20%, 25ml)/瓶、YBS00722011、10g(20%, 50ml)/瓶、YBS00762011、10g(10%, 100ml)/瓶、YBS00742011、5g(10%, 50ml)/瓶、YBS00712011、2g(10%, 20ml)/瓶、YBS00772011、12.5g(25%, 50ml)/瓶、YBS00392009]。
【批准文号】	国药准字S10960052[5g(20%, 25ml)/瓶]、国药准字S10960053[10g(20%, 50ml)/瓶]、国药准字S10960055[10g(10%, 100ml)/瓶]、国药准字S10960056[5g(10%, 50ml)/瓶]、国药准字S10960057[2g(10%, 20ml)/瓶]、国药准字S20043001[12.5g(25%, 50ml)]/瓶。
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# Human Albumin Instructions

Please read through the instructions and follow doctor's advice.

## Warning

The raw material of the product is from human blood plasma. Although it's screened for related infectious agents, and simultaneously, virus removal and inactivation procedure are included in the manufacturing process, such products may still potentially carry along some known or unknown infectious agents, so one must balance risk versus benefit in clinical.

### [Drug Name]

Human Albumin  
Ren Xue Baidanbai

### [Composition]

The product is such a human albumin that is made from healthy human plasma by cold ethanol protein fractionation and deactivating the virus through heating for ten hours at 60°C. It contains a proper quantity of stabilizer, and contains no preservatives or antibiotics.  
Adjuvant: diumsodium caprylate.

[Description] The product should be colorless or pale yellow clear liquid, which may be slightly opalescent, and should not be turbid.

### [Indications]

1. Shock caused by hemorrhage and burn;
2. Raised cranial pressure caused by cerebral edema and wound;
3. Edema or ascites caused by cirrhosis and kidney diseases;
4. Prevention and treatment of hypoproteinemia ;
5. Hyperbilirubinemia of newborn;
6. Used for cardiopulmonary bypass, auxiliary treatment for burn and hemodialysis and adult respiratory distress syndrome.

[Specification] 5g(20%,25ml)/bottle, 10g(20%,50ml)/bottle, 10g(10%, 100ml)/bottle, 5g(10%,50ml)/bottle, 2g(10%,20ml)/bottle, 12.5g(25%,50ml)/bottle.

### [Administrations and Dosage]

Administrations: Gradually adopt intravenous drip or intravenous pushing injection. For preventing body tissue dehydration during massive injection, it is possible to adopt intravenous drip by proper dilution with 5% of glucose injection or sodium chloride injection (it is suitable to use a blood transfusion device with filter screen). The speed of intravenous drip is suitable for not more than 2ml a minute, and it should be especially careful to keep a slow speed during the initial 15 minutes, and after that the speed may be gradually raised to the above-mentioned one.

Dosage: Dosage should be decided by doctor according to the specific condition. Generally, for shock caused by serious burn or loss of blood, it is possible to take a direct injection of 5-10g of this product and 4-6 hours after that to take another injection; for treatment of such chronic albumin-lacking diseases as kidney disease and cirrhosis, it is advised to inject 5-10g of this product daily until edema vanishes and the content of serum albumin returning to the normal level.

### [Adverse Reactions]

There are no adverse reactions generally, though tremble, fever, flushing, tetter or nausea might occur sometimes. Too quick infusion might lead to blood vessel overload, which may cause lung edema. Allergic reaction might occur sometimes.

### [Contraindications]

1. Those who have serious allergy for albumin;
2. Patients of hypertension, acute heart disease and cardio failure of normal blood capacity or high blood capacity;
3. Patients of severe anemia;
4. Those with renal inadequacy.

### [Precautions]

1. The product shall not be used if the liquid becomes turbid, there is sediment, particulate matters or a crack in the glass, the cap becomes loose, or the product becomes invalid;
2. Use the product one-off after opening, and more than one time of usage or applying it in another person is not allowed;
3. If adverse reaction is found during infusion, stop infusion immediately;
4. Patient who suffers severe anhydration shall be supplemented with liquid;
5. Freezing is not allowed during transportation or storage.

### [Pregnancy and Nursing Mothers Use]

Women who are pregnant or going to become pregnant are advised caution in applying the product. If necessary, please follow the doctor's instructions and apply the product under close monitor.

### [Pediatric Use] Uncertain

### [Geriatric Use] Uncertain

[Drug Interactions] It is inadvisable to infuse it mixed with injecta of vasoconstrictive drug, proteolytic enzyme or solvent containing alcohol.

[Overdose] The product has hypertonic function, and excessive injection may cause anhydration, increased load of body circulation, congestive heart failure or lung edema.

### [Pharmacology and Toxicology]

1. Increasing blood volume and maintaining plasma colloid osmotic pressure: albumin accounts for 80% of the plasma colloid osmotic pressure, mainly for adjusting the dynamic balance of water between tissue and vessel. Due to the molecular weight of albumin being comparatively high and osmotic pressure acts as a counterweight to the static pressure of the capillary tube and thus maintaining the normal and constant blood volume. And during the circulation of blood, 1g albumin can maintain 18ml water and the capacity of every 5g albumin for retaining water within circulation corresponds to the function of about 100ml plasma or 200ml whole blood and thus playing the role for increasing the circulating blood volume as well as maintaining the plasma colloid osmotic pressure.

2. Transportation and detoxication: albumin can combine with both negative and positive ions, and can transport different matters as well as transfer poisonous matters into the detoxication organs.

3. Supply of nutrient: tissue protein and plasma can transform into each other. In case of dysbolism of nitrogen metabolism, albumin can supply nutrient to tissue as a nitrogen source.

Toxicology: Uncertain

### [Pharmacokinetics] Uncertain

[Storage] Avoiding from the light at 2-30°C.

[Package] Packing material and container: Glass bottle ; Packing Specification: 1 bottle/case.

[Validity] 36 months.

[Executive Standard] Chinese Pharmacopoeia 2020 Volume 3and [5g(20%,25ml)/ bottle:YBS00722011- 10g (20%,50ml)/ bottle:YBS00762011- 10g(10%, 100ml)/ bottle:YBS00742011- 5g (10%,50ml)/ bottle:YBS00712011- 2g (10%,20ml)/ bottle:YBS00772011- 12.5 g (25%,50ml) / bottle:YBS00392009].

### [Number of Documents of Approval]

GYZZNo.S10960052[5g(20%,25ml)/bottle]- GYZZNo.S10960053[10g(20%,50ml)/bottle]- GYZZNo.S10960055[10g(10%, 100ml)/bottle]- GYZZNo.S10960056[5g(10%,50ml)/bottle]- GYZZNo.S10960057[2g (10%,20ml )/bottle]- GYZZNo.S20043001[12.5 g (25%,50ml) /bottle].

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