GRIFOLS

Albumin (Human) U.S.P. Albutein® 20% Solution

DESCRIPTION:
Albumin (Human) U.S.P., Albutein® 20% Solution is a sterile, aqueous solution for single dose intravenous administration containing 20% human albumin (weight/volume). Albutein® 20% is prepared by a cold alcohol fractionation method from pooled human plasma obtained from venous blood. The product is stabilized with 0.08 millimole sodium caprylate and 0.08 millimole sodium acetyltryptophanate per gram of albumin. Albutein® 20% is osmotically equivalent to four times its volume of normal human plasma. Albutein® 20% contains 130 - 160 milliequivalents of sodium ion per liter and has a pH of 7.0 ± 0.3. The aluminum content of the solution is not more than 200 micrograms per liter during the shelf life of the product. The product contains no preservatives.

Albutein® 20% is heated at 60 °C for ten hours. No positive assertion can be made that this heat treatment completely destroys the causative agents of viral hepatitis, however, there are no known confirmed cases of viral hepatitis which have resulted from the administration of Albutein® 20%.

CLINICAL PHARMACOLOGY:
Albumin is a highly soluble, globular protein (MW 66,500), accounting for 70 - 80% of the colloid osmotic pressure of plasma. Therefore, it is important in regulating the osmotic pressure of plasma.[1,2] Albutein® 20% supplies the oncotic equivalent of approximately 4 times its volume of human plasma. It will increase the circulating plasma volume by an amount approximately 2.5 times the volume infused within 15 minutes, if the recipient is adequately hydrated.[3] This extra fluid reduces hemoconcentration and decreases blood viscosity. The degree and duration of volume expansion depend upon the initial blood volume. When treating patients with diminished blood volume, the effect of infused albumin may persist for many hours. The hemodilution lasts for a shorter time when albumin is administered to individuals with normal blood volume.

Albumin is also a transport protein and binds naturally occurring, therapeutic, and toxic materials in the circulation.[2]

Albumin is distributed throughout the extracellular water and more than 60% of the body albumin pool is located in the extravascular fluid compartment. The total body albumin in a 70 kg man is approximately 320 g; it has a circulating life span of 15 - 20 days, with a turnover of approximately 15 g per day.[1]

INDICATIONS AND USAGE:
Albutein® 20% is indicated:

a. For treatment of hypovolemic shock.[2,4]

b. In conditions in which there is hypoalbuminemia.

c. For burn injuries.

Pediatric Use: The pediatric use of Albutein® 20% has not been clinically evaluated. Therefore, physicians should weigh the risks and benefits of the use of Albutein® 20% in the pediatric population.

CONTRAINDICATIONS:
Albutein® 20% is contraindicated in patients with severe anemia or cardiac failure in the presence of normal or increased intravascular volume.

The use of Albutein® 20% is contraindicated in patients with a history of allergic reactions to this product.

WARNINGS:
Following reports that there exists a risk of potentially fatal hemolysis and acute renal failure from the inappropriate use of Sterile Water for Injection as a diluent for Albumin (Human)[5], if dilution is required, acceptable diluents include 0.9% Sodium Chloride or 5% Dextrose in Water.[6]

Albutein® 20% is made from pooled human plasma. Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases, including a theoretical risk for transmission of Creutzfeldt-Jakob disease (CJD). Although no cases of transmission of viral diseases or CJD have ever been identified for albumin, the risk of infectious agents cannot be totally eliminated. ALL infections thought by a physician possibly to have been transmitted by this product should be reported to the manufacturer at 1-888-GRIFOLS (1-888-474-3657) for USA and 1-323-225-2221 for international. The physician should weigh the risks and benefits of the use of this product and should discuss these with the patient.

Solutions of Albutein® 20% should not be used if they appear turbid or if there is sediment in the bottle. Do not begin administration more than 4 hours after the container has been entered. Discard unused portion.

PRECAUTIONS:
Albutein® 20% should be administered with caution to patients with low cardiac reserve.

Rapid infusion may cause vascular overload with resultant pulmonary edema. Patients should be closely monitored for signs of increased venous pressure.

A rapid rise in blood pressure following infusion necessitates careful observation of injured or postoperative patients to detect and treat severed blood vessels that may not have bled at a lower pressure.

Patients with marked dehydration require administration of additional fluids. Albutein® 20% may be administered with the usual dextrose and saline intravenous solutions. However, solutions containing protein hydrolysates or alcohol must not be infused through the same administration set in conjunction with Albutein® 20% since these combinations may cause the proteins to precipitate.

Pregnancy Category C: Animal reproduction studies have not been conducted with Albutein® 20%. It is also not known whether Albutein® 20% can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Albutein® 20% should be given to a pregnant woman only if clearly needed.

ADVERSE REACTIONS:
The most common adverse reactions include fever and chills, rash, nausea, vomiting, tachycardia and hypotension have also been reported. Should an adverse reaction occur, slow or stop the infusion for a short period of time which may result in the disappearance of the symptoms. If administration has been stopped and the patient requires additional Albutein® 20%, material from a different lot should be used.

Albutein® 20%, particularly if administered rapidly, may result in vascular overload with resultant pulmonary edema.

DOSAGE AND ADMINISTRATION:
Albutein® 20% is administered intravenously. The total dosage will vary with the individual. In adults, an initial infusion of 100 mL is suggested. Additional amounts may be administered as clinically indicated.

In the treatment of the patient in shock with greatly reduced blood volume, Albutein® 20% may be administered as rapidly as necessary in order to improve the clinical condition and restore normal blood volume. This may be repeated in 15 - 30 minutes if the initial dose fails to prove adequate. In the patient with a slightly low or normal blood volume, the rate of administration should be 1 mL per minute.

If dilution of Albutein® 20% is clinically desirable, compatible diluents include sterile 0.9% Sodium Chloride solution or sterile 5% Dextrose in Water.[6]

Pediatric Use: The pediatric use of Albutein® 20% has not been clinically evaluated. The dosage will vary with the clinical state and body weight of the individual. Typically, a dose one-quarter to one-half the adult dose may be administered, or dosage may be calculated on the basis of 0.6 to 1.0 gram per kilogram of body weight (3 to 5 mL of Albutein® 20%). For jaundiced infants suffering from hemolytic disease of the newborn, the appropriate dose for binding of free serum bilirubin is 1 gram per kilogram of body weight which may be administered during the procedure.[7] The usual rate of administration in children should be one-quarter the adult rate.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

DIRECTIONS FOR USE: (50 mL and 100 mL)

When an Administration Set is Used

Flip off plastic cap on top of the vial and expose rubber stopper. Cleanse exposed rubber stopper with suitable germicidal solution, being sure to remove any excess. Observe aseptic technique and prepare sterile intravenous equipment as follows:

1. Close clamp on administration set.
2. With bottle upright, squeeze drip chamber, thrust piercing pin straight through stopper center. Do not twist or angle.
3. Immediately invert bottle, release drip chamber to automatically establish proper fluid level in drip chamber (half full).
4. Attach infusion set to administration set, open clamp and allow solution to expel air from tubing and needle, then close clamp.
5. Make venipuncture and adjust flow.
6. Discard all administration equipment after use. Discard any unused contents.

When an Administration Set is Not Used

Flip off plastic cap on top of the vial and expose rubber stopper. Cleanse exposed rubber stopper with suitable germicidal solution, being sure to remove any excess. Observe aseptic technique and prepare sterile intravenous equipment as follows:

1. Using aseptic technique, attach filter needle to a sterile disposable plastic syringe.
2. Insert filter needle into Albutein® 20%.
3. Aspirate Albutein® 20% from the vial into the syringe.
4. Remove and discard the filter needle from the syringe.
5. Attach desired size needle to syringe.
6. Discard all administration equipment after use. Discard any unused contents.

HOW SUPPLIED:
1. 50 mL vial Albutein® 20%.
2. 100 mL vial Albutein® 20%.

STORAGE:
Albutein® 20% is stable for three years provided that storage temperature does not exceed 30 °C. Protect from freezing.

Rx only

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4. Hauser, C.J., et. al., Oxygen Transport Responses to Colloids and Crystalloids in Critically Ill Surgical Patients, *Surg Gyn Obs*, 150:811-816, June 1980.
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Manufactured by:
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3030734
Printed in USA
Revised January 2010

GRIFOLS

艾爾補定注射液20%

許可証字號：衛署菌疫輸字第000487號

[簡　介]

Albumin (Human) U.S.P., Albutein®20%溶液是一種採靜脈注射方式給藥的滅菌水溶液，每一製劑為單一劑量，含有20%（重量/體積）的人類白蛋白，Albutein®20%是以人類靜脈血經冰酒精分離法 (cold alcohol fractionation method) 製備而成，本品每克白蛋白中加有0.08毫莫耳的 sodium caprylate 及 0.08 毫莫耳的 sodium acetyltryptophanate 作為安定劑，Albutein®20%的滲透壓約相當於四倍的正常人類血漿，每公升含130至160毫克當量的鈉離子，酸鹼值為7.0±0.3，在產品有效期間內每公升溶液之鋁含量不會超過200微克，不含防腐劑。

Albutein®20%曾以攝氏60度加熱十小時，這種加熱處理並不確定可以完全將病毒性肝炎的致病原破壞，但到目前為止並沒有任何因使用Albutein®20%而導致病毒性肝炎發生的確定報告。

[臨床藥理]

白蛋白對水的溶解度很高，為球狀蛋白質，分子量為66,500，血漿中，70至80%的膠滲透壓 (colloid osmotic pressure) 來自於白蛋白，因此在調節血漿滲透壓方面極為重要，Albutein®20%可以提供相當於四倍體積的血漿的補充效果，如果病人已經有給予適當的水份時，輸注後15分鐘之內，循環的血漿將可增加2.5倍於所輸注的Albutein®20%，所增加的液體並可降低血液濃度及黏度，至於體液增量的程度及作用時間則視起初的血量而定，如果是血量不足的病人，則輸注白蛋白的效果可以持續幾個小時，但若病人血量正常則輸注白蛋白後，血液稀釋的效果只能維持較短時間。

白蛋白也是具有運輸能力的蛋白質，於循環中會與治療性和毒性物質自然結合。

一位70公斤重的成年男子約有320公克的白蛋白，其中至少有60%是分佈於全身的細胞外液中，它在循環中存在的時間約為15天至20天，每天約有15公克被代謝掉。

[適應症]

低蛋白血症，休克，燒傷。

[用　法]

Albutein®20%適用於：

a. 治療低血量性休克。

b. 血中白蛋白降低。

c. 燒傷。

小兒科的使用：在小兒科使用上，Albutein®20%未曾被臨床評估過，因此醫師必須衡量使用Albutein®20%的風險及效益。

[禁　忌]

若病人有嚴重貧血或心臟衰竭，但血管內體積仍正常或增加時，不可使用Albutein®20%。病人曾有對Albutein®20%產生過敏反應時，禁止使用。

[警　告]

有報告顯示如果有不適當的使用滅菌用水去稀釋Albumin (Human)有可能引起致命的溶血現象和急性腎衰竭，如果必須稀釋時，則可以 (0.9% Sodium Chloride) 生理食鹽水或是 (5% Dextrose) 葡萄糖，來作稀釋。由於Albutein®20%是由集合人類血漿製成的，經由篩檢捐血者之血漿，和產品製造過程中，經由去活化，去除某些病毒，包括理論上傳染庫賈氏病 (CJD)。雖然並無病例報告顯示使用白蛋白會傳染病毒感染源或CJD，不過，這仍無法完全去除本產品對病毒感染的危險性。所有感染的病人均應向醫師及製造廠報告，電話 1-888-GRIFOLS (1-888-474-3657) (美國) 或 1-323-225-2221 (國際)。醫師必須與病人討論使用此產品之風險及利益。

Albutein®20%溶液若有混濁或沉澱發生時，不可使用，開瓶後四小時內未使用者，應予丟棄。

[注意事項]

心貯量 (cardiac reserve) 低的病人在給予Albutein®20%時應特別小心。輸注速度太快時，會使血管超過負荷，導致肺水腫，因此必須密切注意病人的靜脈壓是否有升高的現象。若病人有受傷或是正值手術後，且輸注本品後有血壓迅速升高的現象時，必須密切注意受傷的血管。病人有明顯脫水時，必須另外補充水分，再者Albutein®20%可以和常用的葡萄糖及生理食鹽輸液併用，但如果是含有蛋白質水解產物或酒精的溶液，則不可和Albutein®20%共同一套輸注器，因為可能導致蛋白質沉澱。

懷孕危害分級C：目前尚沒有以Albutein®20%為對象所做的動物生殖試驗，也不清楚懷孕婦女使用Albutein®20%時是否會對胎兒造成危害或者影響生殖能力，因此除非必要，否則孕婦應避免使用Albutein®20%。

[副作用]

由目前之個案報告中顯示，使用本劑時，常見副作用有寒戰、發燒、發疹、噁心、嘔吐、心跳過速及低血壓等，如果有上述副作用發生時，只須停止使用或將輸注速度調慢，一段短暫時間之後，症狀即會消失，在停藥後，如果有病人仍有必要繼續使用Albutein®20%時，應考慮使用不同批號產品。

使用Albutein®20%時，特別是輸注速度太快時，可能使血管負荷過大，導致肺水腫的發生。

[用量與用法]

Albutein®20%應以靜脈注射方式給藥，而用量則視個別狀況而定，對於成年人，通常建議起始劑量100毫升，其後視症狀是否改善追加。如果是用於治療有嚴重血量減少的休克病人時，應儘可能地採高流速使用。Albutein®20%，以有效改善病人症狀及恢復後正常的血量，因此，一旦起始劑量無法有效改善病人情況時，可在15到30分鐘內重覆給予，對於血量正常或稍減的病人，輸注速度約為每分鐘1毫升。如果臨床上想要稀釋Albutein®20%可用生理食鹽水或5%葡萄糖來作稀釋。

小兒科的用法：Albutein®20%在小兒科的使用上，尚未被臨床評估過。小孩子的使用量則依個別臨床表現及體重而定。一般來說，大約是成人劑量的四分之一或二分之一，如果以體重來計算，每公斤體重應使用0.6至1克 (即3至5毫升的Albutein®20%)，若是因患有新生兒溶血性疾病而產生黃疸的嬰兒欲使用本品以結合血中游離的膽紅素時，則依每公斤體重給予一公克的劑量使用。小孩子的輸注速度則為成人的四分之一。

和一般使用注射藥品的使用方式一樣，注射本劑之前，應先觀察溶液中是否有顆粒性物質存在及變色等問題。

使用方法 (50毫升及100毫升裝)

使用輸注器時

使用時，先將瓶口塑膠蓋拿掉，露出橡皮塞，接著使用適當的滅菌劑消毒橡皮塞的部份，並將殘餘的滅菌劑擦乾，然後按照如下之無菌操作的步驟進行：

1. 將輸注器的夾子關上。
2. 將瓶子瓶口朝上擺放，壓縮緩衝室 (Drip chamber)，然後垂直地將鑽孔針插入橡皮塞中間，但不要扭轉或斜角插入。
3. 將瓶子倒過來，釋放緩衝室，讓輸注液自動流入緩衝室中，然後調整適量的輸注液 (大約是緩衝室容量的一半) 進入緩衝室中。
4. 接上輸注器，打開夾子，將管子及針頭中空氣排掉，再把夾子關上。
5. 開始注射，並將流速做適當調整。
6. 使用後，整組注射器均應丟棄，剩餘的輸注液也不可再用。

不使用輸注器時

使用時，先把瓶口塑膠蓋拿掉，露出橡皮塞，接著使用適當之滅菌劑消毒橡皮塞的部份，並將殘餘的滅菌劑擦乾，然後按照以下無菌操作步驟進行：

1. 應用無菌操作將含有過濾器的針頭接到可拋棄式的塑膠針筒上。
2. 將帶有過濾器的針頭插入Albutein®20%中。
3. 將小瓶中的Albutein®20%抽取到針筒中。
4. 將帶有過濾器的針頭從針筒取下丟棄。
5. 換上適當型號的針頭。
6. 使用後，整個注射器即丟棄，剩餘未用完的注射液也不可再用。

[包　裝]

50毫升裝，100毫升裝Albutein®20%針劑溶液。

[貯　存]

在貯存溫度不超過攝氏30度的情況下Albutein®20%可以保存三年，但不可冷凍保存。

本藥限由醫師使用。

【衛生署公告】

【注意事項】

本品係由人類血漿製得，自人類血漿所製得之產品，可能存在著某些感染源，例如致病性之病毒。藉由篩檢血漿之捐血者，檢驗某些現有病毒感染源，再經由去活化/或去除某些病毒，即可降低此產品傳染感染源之危險性。惟縱然採取上述措施，此類產品仍有可能存在某些未知的感染源，因此，所有感染病人，均應直接向診療醫師及製造廠或代理商報告。請與你的醫師討論使用此產品之風險及利益。

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修訂日期：January 2010　　3030734