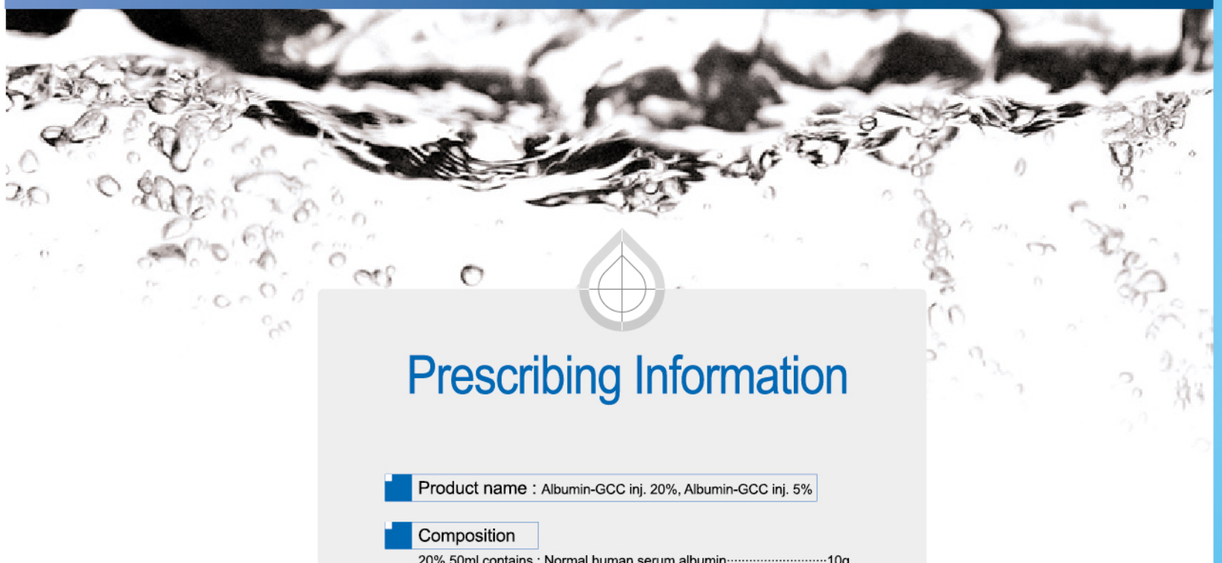
ALBUMIN inj.



Prescribing Information

Product name : Albumin-GCC inj. 20%, Albumin-GCC inj. 5%

Composition

20% 50ml contains : Normal human serum albumin·····10g
20% 100ml contains : Normal human serum albumin·····20g
5% 100ml contains : Normal human serum albumin····· 5g
5% 250ml contains : Normal human serum albumin·····12.5g

Storage

Room temperature (below 30℃, without freezing)
Shelf-life : 39months

How supplied

20%50ml/vial, 20%100ml/vial, 5%100ml/vial, 5%250ml/vial

MANUFACTURED BY
GREEN CROSS
GREEN CROSS

Green Cross Care
Stay healthy and happy with GREEN CROSS CARE

Human Serum Albumin

ALBUMIN inj.

· Plasma Colloid Osmotic Pressure Maintenance
· Intravascular Volume Increase

H_2O

H_2O

Indication

Post OP SAH
Hypoproteinemia
Hypovolemia
Shock
Burns
Pancreatitis and Peritonitis
Adult Respiratory Distress Syndrome
Cardiopulmonary Bypass
Hemolytic Disease of the Newborn
Acute Nephrosis
Acute Liver Failure
Sequestration of Protein Rich Fluids
Erythrocyte Resuspension
Renal Dialysis

녹십자 GREEN CROSS

1 Feature of Albumin

- This product is heat-treated at 60℃ for 10 hours. This heat treatment destroys the causative agents of viral hepatitis and AIDS
- 10g of Human serum albumin provides 174ml of plasma increase
- Requires no typing or crossmatching
- In case 20ml of Human serum albumin is administered, approx. 60ml of tissue liquid is added to blood vessel within 15 minutes. This causes the decrease of blood concentration and viscosity of liquid
- This product is effective for the treatment of hypoproteinemia accompanying edema, hepatic cirrhosis or renal inadequacy etc.
- This product is effective to the cerebra edema patients who should restrict taking hypertonic fluid or water

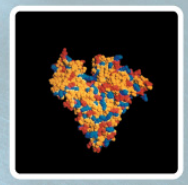
2 Albumin Pharmacology

ALBUMIN Inj.

- Principle function of Albumin is to keep blood volume
- Albumin takes charge of osmotic pressure of plasma at 70~80%
- Albumin transports drugs through blood vessels
- Albumin is used to remove toxic bilirubin from hemolytic disease of fetus(new born)
- Albumin transports fatty acids, hormones and enzymes
- In case albumin concentration was <35g/L, 35-40g/L, >40g/L in male patients(40~96 years old), annual mortality rate was 50%, 43%, 11% [1)]
- Albumin concentration was increased as >42g/L(higher than normal concentration) to the 4,100 patients(older than 70). As the results, higher concentration of albumin was related to low mortality

  In case albumin concentration is >43g/L, it is presumed that mortality is decreased at 20% of male patients and 40% of female patients comparing to 41~43g/L [2)]

Goldwasser P, Feldman J J Clin Epidemiol 1997;50:693-703.
Rainey TG, Read CA. The pharmacologic approach to the critically ill patient. 3rded. Baltimore: Williams & Wilkins; 1994. P272-90.
Griffel MI, Kaufman BS. CritCare Clin 1992;8:235-53.
Wagner BK, D'Amelio LF. Clin Pharm 1993;12:335-46
Gonzalez ER, Kennewurf BS. US Pharmacist December 1998:1-12
1) Rudman, D., Feller, A.G., Nagraj, H.S., Jackson, D.L., Rudman, I.W., and Mattson, D.E. (1987). Relation of serum albumin concentration to death rate in nursing home men. JPEN, J. Parenter. Enteral. Nutr.11, 360-363.
2) Corti, M. -C., Guralnik, J.M., Salive, M.E., and Sorkin, J.D. (1994). Serum albumin level and physical disability as predictors of mortality in older persons. JAMA, J.Am. Med. Assoc. 272, 1036-1042.



· Space-filling model of human albumin molecule

· X-ray crystallography of human albumin

3 Albumin Safety

4 Clinical Study

ALBUMIN inj.

· Albumin has longest safety records among plasma derivatives

· There has been no case of hepatitis B, hepatitis C or HIV infection during past 30 years

· Pasteurization (at 60℃ for 10 hours) method was proved to inactivate HVB, HCV, HIV etc

Validation Study for the Inactivation/Removal of Virus*

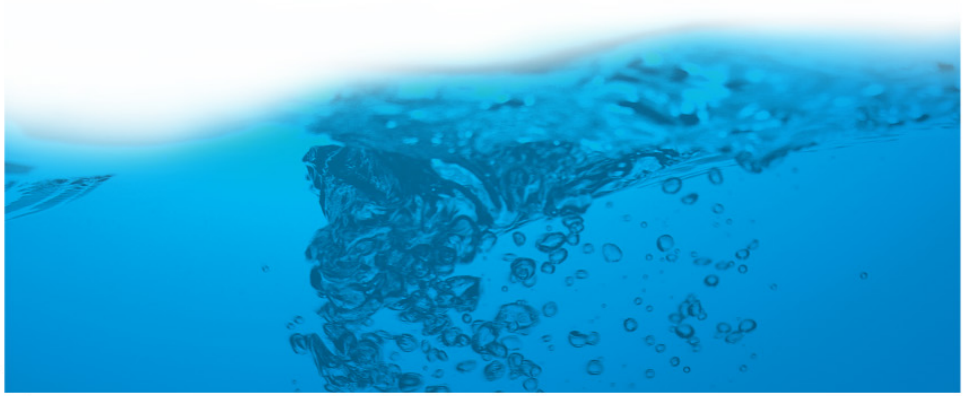
Fraction IV precipitation or Ethanol inactivation

Virus	HIV	BVD	BHV	EMC	PPV
Total clearance	≥4.5±0.4	4.9±0.4	≥6.9±0.3	5.8±0.4	3.7±0.4
Total clearance (duplicate)	≥4.5±0.4	≥5.2±0.2	≥6.9±0.3	5.1±0.4	3.9±0.4

60℃ heat treatment

Virus	HIV	BVD	BHV	EMC	PPV
Total clearance	5.2±0.3	5.7±0.4	≥7.3±0.4	≥7.1±0.3	1.7±0.5
Total clearance (duplicate)	≥6.5±0.3	≥6.4±0.4	≥7.4±0.4	5.2±0.4	1.4±0.4

Colgan K, Moody ML, Witte K. Am J Health Syst pharm 2000;57:2094-8.
Tabor E. Transfusion 1999;39:1160-8
*Ref. Validation Study for the Inactivation/Removal of HIV, BVD, BHV, EMC and PPV During the Fraction IV Precipitation and Pateurisation Steps of the Sponsor's Manufacturing Process for Albumin. Q-One Biotech.



High level of albumin decreases risk of poor-outcome at acute stroke patients

	Patients with Poor Outcome (N=266)	Patients with Nonpoor Outcome (N=493)	P
SSS Score on admission, mean(SD)	19.7 (12.8)	41.5 (10.8)	<0.01
Albumin g/L, mean(SD)	34.1 (7.4)	36.8 (6.7)	<0.01

SSS : Scandinavian Stroke Scale.

Ref. Serum Albumin Level as a Predictor of Ischemic Stroke. Outcome, Dziedzic T, Slowik A, Szczudlik A, Stroke 2004; 35: 156 - 158

After albumin administration to SAH patients, cerebro vascular spasm was decreased, clinical result was improved, and hospital cost was decreased

	Albumin (N=37)	Nonalbumin (N=47)	P
In-hospital deaths (%)	2 (5.4)	9 (19)	0.07
Symptomatic vasospasm (%)	7 (19)	13 (28)	0.2

	Group 1 (N=63)	Group 2 (N=77)	P
Cost data (US $ x 1000)	62.0±39.0	81.0±49.0	0.02
total hospital laboratory	3.7±2.9	4.4±3.5	0.3
radiology	15.0±12.0	23.0±16.0	<0.01

* Group 1 included patients treated between May 1998 and May 1999;
Group 2 patients were treated between June 1999 and May 2000.
Since May 1999, patients with SAH have been treated only with crystalloids in NSU.

Ref. Effect of human albumin administration on clinical outcome and hospital cost in patients with suba rachnoid hemorrhage, Suarez JI, shannon L, Zaidat OO, Suri MF, Singh G, Lynch G, Selman WR, Journal of neuro surgery 2004; 100: 585 - 590.

After albumin administration to shock patients, cardiac index, oxygen transport, and oxygen consumption were increased comparing to ringer's lactate solution or packed red blood cell

	Shole blood (1 unit) n=86	Albumin (500 mL) n=82	LR (1,000 mL) n=35	PRBCs (1 unit) n=32
CI ($L/min/m_2$)	0.44	**0.67**	0.23	0.02
DO_2 ($L/min/m_2$)	87	**65**	-3	64
VO_2 ($L/min/m_2$)	24	**10**	0	7

CI : cardiac index, DO_2 : oxygen delivery, VO_2 : oxygen consumption
LR : lactated Ringeres solution, $PRBC_s$: packed red blood cells

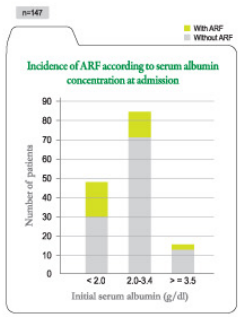
Ref. Circulatory Effects of Whole Blood, Packed Red Cells, Albumin, Sarch, and Crystalloids in Resuscitation of Shock and Acute Critical Illness, Shoemaker WC, Wo CCJ. Vox Sang 1998;74:69-74.

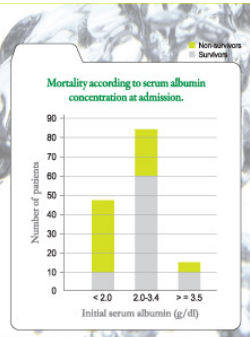
After albumin administration with cefotaxime concomitantly to patients of induration and idiopathic bacterial peritonitis, renal disorders and mortality were markedly decreased comparing to cefotaxime administration alone

	Cefotaxime (n=63)	Cefotaxime+Albumin (n=63)	*P* value
Renal impairmant	33%	10%	0.002
In-hospital mortality	29%	10%	0.01
Mortality at 3 months	41%	22%	0.03

Ref. Effect of Intravenous Albumin on Renal Impairment and Mortality in Patients with Cirrhosis and Spontaneous Bacterial Peritonitis.

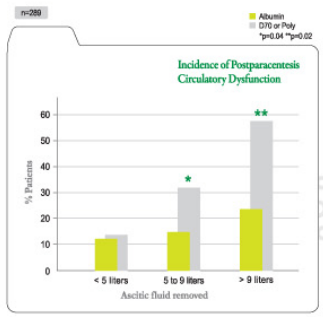
Low concentration of albumin at early stage of severe burn patients increases mortality of acute renal failure and mortality





Ref. Impact fo Burn Size and Initial Serum Albumin Level on Acute Renal Failure Occurring in Major Burn. Kim GH, Oh KH, Yoon JW, Koo JR, Kim HJ, Chae DW, Noh JW, Kim JH, Park YK. Am J Nephrol 2003;23:55-60

After albumin administration to cirrhosis patients, who received ascites paracentesis, dyscyclia was markedly decreased comparing to dextran 70 or ploygeline



Ref. Randomized Trial Comparing Albumin, Dextran 70 and Polygeline in Cirrhotic Patients with Ascites Treated by Paracentesis. Gines A, Fernandez-Esparrach G, Monescillo A, Vila C, Domenech E, Abecasis R, et al. Gastroenterology 1996;111:1002-10