건 명	Albumin 20% 인서트(인도네시아 등록용)		
규 격 (가로x세로)	100x267mm	Q A	오창
		표시문안	7pt
색 상	먹 1도	후 가 공	
업체제작일	2025.09.24.	작 업 처	(주)트리스톤

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칼선 PANTONE 185C

※인쇄진행시, 인쇄사양과 다를경우
녹십자로 즉시 연락주시기 바랍니다.

Albumin inj. 20% - GCC

(Normal Serum Albumin, Human)

[Description]

A 20% solution of purified human serum albumin is manufactured from normal plasma by the cold ethanol blood fractionation method. After purification, stabilization and passage twice through a sterilizing filter, it is heated at 60°C for 10 hours. This heat treatment destroys the causative agents such as Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Human Immunodeficiency Virus (HIV), and so on. There are no known cases of viral disease which have resulted from the administration. This product contains no preservative and is free from plasma proteins associated with the blood clotting mechanism and blood group antibodies.

[Appearance]

Albumin inj. 20% - GCC is a transparent and colorless vial which contains clear, almost colorless, yellow, pale yellowish or pale greenish liquid for injection. This liquid contains human normal serum albumin.

[Composition]

Each vial 50 ml contains,

Normal human serum albumin ····· 10g
Sodium caprylate ····· 0.13295g
N-Acetyl tryptophan ····· 0.197g
Sodium chloride ····· q.s.
Sodium hydroxide (as Na 3.3 mg/ml) ····· q.s.
Water for injection ····· q.s.

Each vial 100 ml contains,

Normal human serum albumin ····· 20g
Sodium caprylate ····· 0.2659g
N-Acetyl tryptophan ····· 0.3940g
Sodium chloride ····· q.s.
Sodium hydroxide (as Na 3.3 mg/ml) ····· q.s.
Water for injection ····· q.s.

[Indication]

Restoration and maintenance of circulating blood volume where volume deficiency has been demonstrated and use of a colloid is appropriate.

[Dosage & Administration]

The usual dosage is 25 ~ 75 g (125 ~ 375 mL at 20%) per day.
It should be slowly administered by drip infusion or direct intravenous infusion at a rate of 2 – 4 mL per minute.
The total dosage will vary by body weight, age and symptom.

[Precaution]

1. Special warnings

Albumin inj. 20% - GCC, manufactured from human plasma, has the potential to transmit hepatitis viruses or other transmissible agent (theoretically, CJD) which can cause infection. The risk of virus infection cannot be entirely eliminated. Accordingly, patients with hemophilia or immunodeficiency are recommended to be appropriately vascinated (Hepatitis A vaccine, etc), and the attending physician should monitor patients regularly to check for any signs of virus infection. Since Albumin inj. 20% - GCC. has potential risk as described above, the risk of virus infection can't be eliminated entirely. Therefore, the patient should be fully informed at the time of administration, and should only use the minimum amount necessary for treatment after careful consideration of the therapeutic need.

2. Contraindications

Patients with history of hypersensitivity to ingredients of Albumin Inj. 20% – GCC.

3. Special precautions

1) Patients with cardiac dysfunction (cardiac overload may occur due to increase in circulating plasma volume)
2) Patients with excessive circulating plasma volume (Rapid administration may cause circulatory disorder (Cardiac burden, etc.) or pulmonary edema.)
3) Patients with hemolytic anemia or anemia from blood loss (human parvovirus B19 infection may occur. In case of infection, critical systemic symptoms with fever and acute severe anemia may occur.)
4) Patients with immunological incompetence or immunodeficiency (human parvovirus B19 infection may occur. In case of infection, continuous anemia may occur.)

4. Undesirable Effects

1) Hypersensitivity : fever, hot flush, urticaria
2) Shock : since shock may occur, the patients must be carefully observed so that when dyspnea, wheeze, chest discomfort, decrease in blood pressure, weak pulse or cyanosis occur, administration should be discontinued followed by proper treatment.
3) Others : Chill, back pain, etc.

5. General precautions

1) In present plasma fractionation process, it is difficult to completely inactivate or remove human parvovirus B19 and etc. Accordingly, possibilities of infection cannot be disregarded, and special caution should be taken for catamnesis.
2) Albumin synthesis may not be properly operated in chronic disease patients. Particularly, albumin synthesis may be prohibited at ≥ 4 g/dL of serum albumin.
3) Circulating plasma volume may increase sharply. Administration rate should be controlled, and cautions should be taken for the pulmonary edema and heart failure etc. For references, following increase in circulating plasma volume can be observed with every 50 mL injection of albumin products; 200 mL for 20% products.
4) Target concentration of serum albumin should be ≥ 3.0 g/dL (in acute) or ≥ 2.5 g/dL (in chronic). Before administration, the necessity should be clearly considered. Serum albumin concentration and clinical improvement should be studied comparing pre and post administration. And cautions should be taken in order not to make unnecessary administration.
5) Even though safety plan for the prevention of the spread of infection is prepared, risk of infection cannot be entirely disregarded since this product originated from human blood. This should be explained to patients.
6) In case of hypoalbuminemia by chronic diseases (hepatic cirrhosis, etc.), even though albumin is administered, serum albumin does not stay in the blood vessel and leaked out of blood vessel. Accordingly, the concentration of serum albumin does not increase than expected, further more albumin degradation may occur. Caution is needed.

6. Pregnancy and lactation

Safety for pregnant women has not been established. The possibilty of parvovirus B-19 infection cannot be excluded from the administration of Albumin injection 20% - GCC. In case of parvovirus B-19 infection, fetal disturbances (abortion, hydrops fetalis, fetal death) may occur. Albumin inj. 20% - GCC should be given to a pregnant women only if the expected benefit justifies the possible risk.

7. Pediatric use

Safety for low birth weight infants and neonates has not been established.

8. Geriatric use

Since elderly patients generally have low physiological function, this product should be administered with special care.

9. Cautions in application

1) If particulate matter is observed, or color is not clear, it should be discarded.
2) Injection site should be farthest from the infection or injured part.
3) Avoid mixing with other medicinal products except for fluids which is close to neutral such as 5%-Glucose, normal saline or electrolyte solution, etc.
4) Discard the unused portion. Do not use the remaining solution due to the concern of microbial contamination. (Because proteins in Albumin inj. 20% - GCC. are an environment in which microorganisms can grow easily as it does not contain preservatives).

10. Others

This product does not contain blood coagulation factors.

[Storage and Expiration Date]

Store ≤ 30°C in hermetic container without freezing and can be used for 39 months from the date of manufacture.

[How supplied]

Albumin inj. 20% - GCC : Box, 1 vial @ 50 mL
Reg. No. DKI2060501149A1
Albumin inj. 20% - GCC : Box, 1 vial @ 100 mL
Reg. No. DKI2060501149A1

ON MEDICAL PRESCRIPTION ONLY

Manufactured by :

GC Biopharma

GC Biopharma Corp.
586, Gwahaksaneop 2-ro, Ochang-eup, Cheongwon-gu,
Cheongju-si, Chungcheongbuk-do, Korea

Imported by :

FAHRENHEIT

PT. PRATAPA NIRMALA
Tangerang - Indonesia

Ins-06-211-1
Ins-06-161-1

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