Size : 59×59×114mm

Pantone 299 | Pantone 186 | Pantone 158 | K

CA1F_0401_01

100mL

SK Albumin 20% Infusion

Human Albumin 200g/l (20%)

SK plasma

SK Albumin 20% Infusion

A

Human Albumin 200g/l (20%)

FOR INTRAVENOUS ADMINISTRATION ONLY

100mL

【STORAGE CONDITION】

Keep the vial in the outer carton.
Store below 30 °C. Do not freeze.
Protected from light.

HET
Harus dengan resep dokter

Reg. No. :

Lot No. :
Mfg. Date :
Exp. Date :

SK plasma

SK Albumin 20% Infusion

A

Human Albumin 200g/l (20%)

FOR INTRAVENOUS ADMINISTRATION ONLY

100mL

【COMPOSITION】

Each 100mL contains;

Human albumin	20g
N-acetyl-DL-tryptophan	0.3940g
Sodium caprylate	0.2659g
Sodium chloride	q.s.
Sodium hydroxide	q.s.
Water for Injection	q.s.

See the enclosed package insert for the detailed information.

Manufactured by
SK plasma
SK Plasma Co., Ltd.
157, Saneopdanji-gil, Pungsan-eup, Andong-si, Gyeongsangbuk-do, Korea

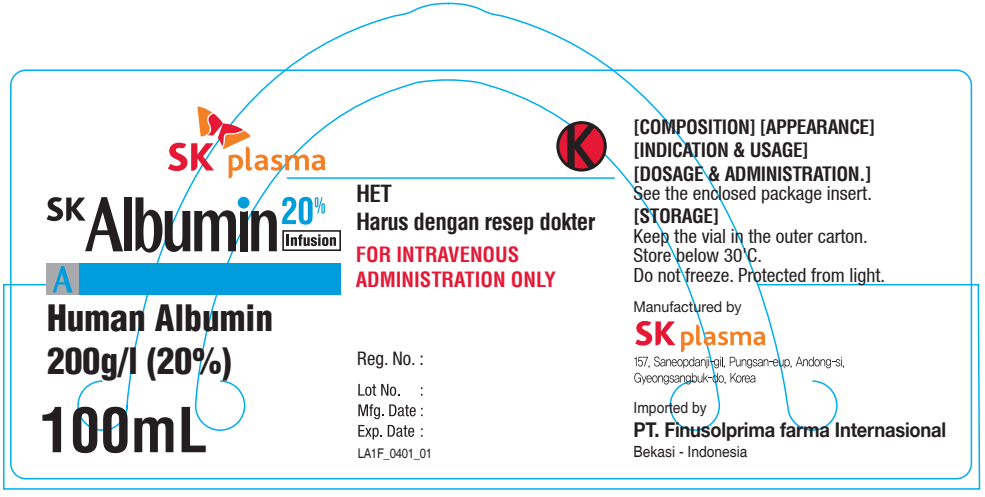
Imported by
PT. Finusolprima farma Internasional
Bekasi - Indonesia

DISETUJUI OLEH BPOM: 21/11/2024

ID: EREG100225VR12400030

Albumin LABEL 100mL
Size : 127×54mm

Pantone 299 | Pantone 186 | Pantone 158 | K



DISETUJUI OLEH BPOM: 21/11/2024

ID: EREG100225VR12400030

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

SK ALBUMIN 20% (Human Albumin 20%)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial of 100 ml contains 20g of human albumin.

For excitement, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for infusion.
A clear, slightly viscous liquid; it is almost colourless, yellow, amber or green in a colorless and transparent bottle.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

SK ALBUMIN 20% Injection is indicated for restoration and maintenance of circulating blood volume where volume deficiency has been demonstrated, and use of a colloid is appropriate

4.2 Posology and method of administration

The concentration of the albumin preparation, dosage and the infusion-rate should be adjusted to the patient's individual requirements.

Posology

The dose required depends on the size of the patient, the severity of trauma or illness and on continuing fluid and protein losses. Measures of adequacy of close required. If human albumin is to be administered, haemodynamic performance should be monitored regularly; this may include;.

- Arterial blood pressure and pulse rate
- Central venous pressure
- Pulmonary artery wedge pressure
- Urine output
- Electrolyte
- Haematocrit/ haemoglobin

Method of administration

Human albumin can be directly administered by the intravenous route, or it can also be diluted in 5% glucose or 0.9 % Sodium Chloride

The infusion rate should be adjusted according to the individual circumstances and the indication. In plasma exchange the infusion - rate should be adjusted to the rate of removal.

4.3 Contraindications

Patients with history of allergic reaction to this drug and its ingredients

4.4 Special warnings and precautions for use

Suspicion of allergic or anaphylactic type reactions requires immediate discontinuation of the injection. In case of shock, standard medical treatment for shock should be implemented. Albumin should be used with caution in conditions where hypervolaemia and its consequences or haemodilution could represent a special risk for the patient. Examples of such conditions are:

- Decompensated cardiac insufficiency
- Hypertension
- Oesophageal varices
- Pulmonary oedema
- Haemorrhagic diathesis
- Severe anaemia
- Renal and post-renal anuria

Use in caution in patients with immunodeficiency (The risk of Human Parvovirus B19 infection cannot be eliminated. When infected, patients could have symptoms of prolonged anemia)

200–250 g/l human albumin solutions are relatively low in electrolytes compared to the 40–50 g/l human albumin solutions. When albumin is given, the electrolyte status of the patient should be monitored (see section 4.2) and appropriate steps taken to restore or maintain the electrolyte balance.

Albumin solutions must not be diluted with water for injections as this may cause haemolysis in recipients.

If comparatively large volumes are to be replaced, controls of coagulation and haematocrit are necessary. Care must be taken to ensure adequate substitution of other blood constituents (coagulation factors, electrolytes, platelets and erythrocytes).

Hypervolaemia may occur if the dosage and infusion rate are not adjusted to the patient's circulatory

situation. At the first clinical signs of cardiovascular overload (headache, dyspnoea, jugular vein congestion), or increased blood pressure, raised venous pressure and pulmonary oedema, the infusion is to be stopped immediately.

General cautions

1) Under the current production process of plasma derivatives, human parvovirus B19 cannot be completely deactivated or eliminated and the possibility of infection cannot be eliminated. Therefore, attention must be paid to the progress after the administration.
2) For the treatment of chronic diseases, its administration could lower the ability of albumin synthesis. In particular, when the concentration of albumin is above 4g/dL, the albumin synthesis could be restrained.
3) As the circulating plasma volume rapidly increase during the administration speed of injection should be regulated and pay attention to the outbreak of pulmonary edema and heart failure. For the reference, circulating plasma volume is increased by 200 mL for 20% drug, and 250mL for 25% drug when injecting 50mL of this drug.
4) The concentration of target serum albumin after the administration should be at least 3.0g/dL for acute conditions and 2.5g/dL for chronic conditions. Before administration, the necessity of administration must be clarified. The albumin concentration (before and after the administration) and the clinical improvement must be compared. After the administration, physicians should review the medical necessity carefully to prevent unnecessary continuous use.
5) Along with the necessity of this drug in the treatment of the disease, it should also be explained to the patient that, although certain safety measures are applied in the production process of this drug in order to prevent infection, the risk of infection derived from human blood cannot be excluded completely.
6) In case of hypoalbuminemia caused by chronic diseases such as liver cirrhosis, the concentration of albumin does not increase as expected since the injected albumin tends to flow out of the blood vessel. In this case, caution must be taken since the decomposition of albumin is accelerated. As this drug is produced from human blood plasma, at the present level of scientific technology, the risk of infection by blood borne virus or other kinds of infectious agent (theoretically CJD) cannot be eliminated. Accordingly, appropriate vaccinations such as Hepatitis A vaccination are recommended to hemophilic patients or those with very low immune functions. When medicating, doctors should monitor periodically for any signs of infection. Since human blood is used as the source of the drug the possibility of infection cannot be entirely excluded. In this reason doctors must fully explain the risks and minimize the administration to patients after careful review of the necessity.
7) Standard measures to prevent infections resulting from the use of medicinal products prepared from

human blood or plasma include selection of donors, screening of individual donations and plasma pools for specific markers of infection and the inclusion of effective manufacturing steps for the inactivation/ removal of viruses. Despite this, when medicinal products prepared from human blood or plasma are administered, the possibility of transmitting infective agents cannot be totally excluded. This also applies to unknown or emerging viruses and other pathogens.

4.5 Interactions with other medicinal products and other forms of interactions

No specific interactions of human albumin with other medicinal products are known.

4.6 Fertility, pregnancy and lactation

The safety of SK ALBUMIN 20% Injection for use in human pregnancy has not been established in controlled clinical trials. However, clinical experience with albumin suggests that no harmful effects on the course of pregnancy, or on the foetus and the neonate are to be expected.

The possibility of human Parvovirus B19 infection risk cannot be eliminated when administered. Since the fetus could develop disorders (miscarriage, hydrops fetalis, fetal death) when infected, the drug must be administered to patients who are pregnant or with possibility of pregnancy only when the benefits of the treatment outweigh the possible risks.

No animal reproduction studies have been conducted with SK ALBUMIN 20% Injection.

Experimental animal studies are not available to assess the safety with respect to reproduction, development of the embryo or foetus, the course of gestation and peri-and postnatal development. However, human albumin is a normal constituent of human blood.

4.7 Effects on ability to drive and use machines

No effects on ability to drive and use machines have been observed.

4.8 Undesirable Effects

1) Hypersensitivity reactions including; fever, hot flush and hives.
2) Shock: It could cause shock, therefore, sufficient observation must be given and the administration should be stopped immediately and proper measures should be taken if symptoms such as dyspnea, wheezing, chest pain, hypotension, acrotism and cyanosis are observed.
3) Others symptoms of the following could be experienced: chills, lumbago.

As this drug is produced from human blood plasma, at the present level of scientific technology, the risk of infection by blood borne virus or other kinds of infectious agent (theoretically CJD) cannot be eliminated. Accordingly, appropriate vaccinations such as Hepatitis A vaccination are recommended to hemophilic patients or those with very low immune functions. When medicating, doctors should

monitor periodically for any signs of infection. Since human blood is used as the source of the drug the possibility of infection cannot be entirely excluded. In this reason doctors must fully explain the risks and minimize the administration to patients after careful review of the necessity.

4.9 Overdose

Hypervolaemia may occur if the dosage and rate of infusion are too high. At the first clinical signs of cardiovascular overload (headache, dyspnoea, jugular vein congestion), or increased blood pressure, raised central venous pressure and pulmonary oedema, the infusion should be stopped immediately and the patient's haemodynamic parameters carefully monitored.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: plasma substitutes and plasma protein fractions, ATC code: B05AA01
Human albumin accounts quantitatively for more than half of the total protein in the plasma and represents about 10 % of the protein synthesis activity of the liver.

The most important physiological functions of albumin results from its contribution to oncotic pressure of the blood and transport function. Albumin stabilises circulating blood volume and is a carrier of hormones, enzymes, medicinal products and toxins.

5.2 Pharmacokinetic properties

Under normal conditions, the total exchangeable albumin pool is 4-5 g/kg body weight, of which 40-45 % is present intravascularly and 55-60 % in the extravascular space. Increased capillary permeability will alter albumin kinetics and abnormal distribution may occur in conditions such as severe burns or septic shock.

Under normal conditions, the average half-life of albumin is about 19 days. The balance between synthesis and breakdown is normally achieved by feedback regulation. Elimination is predominantly intracellular and due to lysosome proteases.

In healthy subjects, less than 10 % of infused albumin leaves the intravascular compartment during the first 2 hours following infusion. There is considerable individual variation in the effect on plasma volume. In some patients the plasma volume can remain increased for some hours. However, in critically ill patients, albumin can leak out of the vascular space in substantial amounts at an unpredictable rate.

5.3 Preclinical safety data

No animal studies have been conducted with SK ALBUMIN 20% injection.

Human albumin is a normal constituent of human plasma and acts like physiological albumin.

In animals, single dose toxicity testing is of little relevance and does not permit the evaluation of toxic or lethal doses or of a dose-effect relationship. Repeated dose toxicity testing is impracticable due to the development of antibodies to heterologous protein in animal models.

To date, human albumin has not been reported to be associated with embryo-foetal toxicity, oncogenic or mutagenic potential.

No signs of acute toxicity have been described in animal models.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Caprylate
N-Acetyl-D,L-Tryptophan
Sodium Chloride
Sodium Hydroxide
Water for Injection (Adjust total sodium content to 330mg)

6.2 Incompatibilities

Human albumin must not be mixed with other medicinal products (except those mentioned in 6.6)

6.3 Shelf-life

39 months from the date of manufacture.

6.4 Special precautions for storage

Keep the vial in the outer carton. Store below 30°C. Do not freeze. Protected from light.

6.5 Nature and contents of container

Glass bottle (EP Type II glass) and Rubber stopper

50 mL/container, 100 mL/container

6.6 Special precautions for disposal and other handling

The solution can be directly administered by the intravenous route, or it can also be diluted in an isotonic solution (e.g. 5 % glucose or 0.9 % sodium chloride).

Albumin solutions must not be diluted with water for injections as this may cause haemolysis in recipients.

If large volumes are administered, the product should be warmed to room or body temperature before use.

Do not use solutions which are cloudy or have deposits. This may indicate that the protein is unstable or that the solution has become contaminated.

Once the container has been opened, the contents should be used immediately. Any unused product should be disposed of in accordance with local requirements

7. Presentation/ Package:

Dus, Vial @ 50 mL

Reg Number:

Dus, Vial @ 100 mL

Reg Number:

8.Registered & distributed by:

PT Finusolprima Farma Internasional

Jl. Raya Bekasi Km. 28,5 Kawasan Industri Rawa Pasung, Kota Baru, Bekasi Barat, Kota Bekasi 17133, Indonesia

9. Manufactured by:

SK Plasma Co., Ltd.

157 Saneopdanji-gil, Pungsan-eup, Andong-si, Gyeongsangbuk-do, Republic of Korea, 36618

10. Peringatan Khusus:

Harus dengan resep dokter

SK ALBUMIN 20%

Infus

INFORMASI PRODUK UNTUK PASIEN

Apakah **SK ALBUMIN 20% infus** ?

SK ALBUMIN 20% infus adalah produk obat yang berbentuk injeksi dalam sediaan vial 100 mL atau 50 mL yang mengandung albumin manusia sebesar 20%.

Untuk apa **SK ALBUMIN 20% infus** diberikan kepada pasien ?

Diberikan untuk kondisi pasien yang mengalami defisiensi/kekuragan volume darah pada peredaran darahnya, dimana **SK ALBUMIN 20% infus** dapat mengembalikan dan memelihara volume di dalam peredaran darah

Berapa dosis yang diberikan **SK ALBUMIN 20% infus** kepada pasien ?

Dosis **SK ALBUMIN 20% infus** yang dibutuhkan tergantung pada ukuran individual pasien dengan memperhitungkan tingkat keparahan penyakit dan tingkat penurunan volume peredaran darah pasien yang terjadi. Sebelum **SK ALBUMIN 20% infus** diberikan, dokter akan menganalisa dan memperhitungkan dosis dan laju infus kebutuhan pasien

Bagaimana cara pemberian **SK ALBUMIN 20% infus** ?

SK ALBUMIN 20% infus dapat diberikan langsung atau dapat diencerkan menggunakan cairan infus glukosa 5% atau cairan infus sodium klorida 0.9% yang diberikan melalui jalur pembuluh darah vena, dengan tetesan laju infus akan disesuaikan dengan keadaan individu pasien

Kepada siapa **SK ALBUMIN 20% infus** tidak boleh diberikan ?

SK ALBUMIN 20% infus tidak boleh diberikan kepada pasien yang memiliki riwayat alergi terhadap kandungan obat ini.

Apa saja yang perlu diperhatikan saat menggunakan **SK ALBUMIN 20% infus** ?

Pada saat pemberian dipertukan suatu monitor yang ketat mengenai status keseimbangan komponen dalam darah pasien.

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Obat-obatan atau makanan apa saja yang harus dihindari saat menggunakan **SK ALBUMIN 20% infus** ?

Tidak ada obat-obatan atau makanan yang harus dihindari secara spesifik saat menggunakan **SK ALBUMIN 20% infus.**

Apakah dapat berpengaruh kepada kesuburan, Wanita hamil dan menyusui?

Belum ada peneli tian **SK ALBUMIN 20% infus** terhadap reproduksi hewan, wanita hamil dan menyusui, sehingga belum diketahui keamanannya. Namun, komposisi **SK ALBUMIN 20% infus** adalah albumin manusia yang erupakan komponen normal di dalam darah manusia.

Apakah ada efek terhadap kemampuan mengendarai kendaraann atau menggunakan mesin dalam penggunaan **SK ALBUMIN 20% infus** ?

Tidak teramati adanya efek terhadap kemampuan dalam mengendarai kendaraan atau menggunakan mesin.

Apakah ada efek yang tidak diinginkan yang mungkin terjadi ?

- Reaksi alergi seperti demam, rasa paras di wajah dan gatal
- Keadaan yok ([kesultan bernafas, mengi/nafas berbunyi, tensi darah menurun cepat, membiru) dimana pemberian infus harus segera dihentikan dan segera ditangani
- Mengigil, sakit pingang dan mual
- Adanya risiko tertular agen infeksius yang tidak dapat dieliminasi menggunakan teknologi yang ada saat ini yang terkandung dalam plasma albumin donor (infeksi human Parvovirus B19)

Apakah tanda bila terjadi kelebihan dosis ?

Yang.terjadi adalah kapasitas jantung yang berlebih dengan gejala seperti sakit kepala, kesulitan bernafas, pembesaran vena jugularis, peningkatan tekanan darah atau pembuluh darah vena sentral dan terbentuknya cairan didalam paru-paru.

Bagaimana cara penyimpanan **SK ALBUMIN 20% infus** ?

SK ALBUMIN 20% infus disimpan dalam suhu dibawah 30^{o}C namun tidak boleh beku

Bagaimana pemerian **SK ALBUMIN 20% infus** ?
Cairan bening, sedikit kental, hampir tidak berwarna.

SK ALBUMIN 20% infus didaftarkan dan didistribusikan oleh PT Finusolprima Farma Internasional yang beralamat di Jalan Raya Bekasi KM 28.5, Kawasan Industri Rawa Pasung, Kotabaru, Bekasi Barat, Kota Bekasi, Indonesia.

SK ALBUMIN 20% infus dibuat oleh SK PLASMA CO.LTD (Korea) yang beralamat di 157, Saneopdanji-gil, Pungsan-eup, Andong-si, Gyeongsangbuk-do, Republic of Korea, 36618.

SK ALBUMIN 20% infus memiliki peringatan khusus yaitu Harus dengan resep dokter

Nomor Izin Edar:

Kemasan **SK ALBUMIN 20% infus**;
Dus, Vial @ 50 ml
Dus, Vial @ 100 ml