160 X 160mm K

Albumin SG Injection 20%

(Human Serum Albumin)

SK plasma

[COMPOSITION] Each 100mL contains

Human serum 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.

[PRODUCT DESCRIPTION]

Almost colourless or yellow, light yellow or light green coloured transparent solution for injection containing human serum albumin, in a colourless and transparent vial

Albumin SG Injection 20% is manufactured from human plasma donated by Singapore's voluntary and non-remunerated donors.

[INDICATIONS]

Hypoalbuminemia caused by albumin loss (burn, nephrotic syndrome, etc), dysfunction of albumin synthesis (liver cirrhosis, etc) and haemorrhagic shock

[DOSAGE AND ADMINISTRATION]

Albumin SG Injection 20% 125-375mL, equivalent to human serum albumin 25-75g should be administered by intravenous drip infusion or by slow direct intravenous injection. The recommended infusion rate is 2-4mL/min. It may be diluted with 5% glucose and 0.9% sodium chloride when necessary. The dosage may be adjusted according to body weight, age and symptoms.

[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.

[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.

[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.

[INTERACTIONS WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTIONS]

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

[WARNING]

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.

There are no reports of virus transmissions with albumin manufactured to specifications by established processes.

It is strongly recommended that every time that Albumin SG Injection is administered to a patient, the name and batch number of the product are recorded in order to maintain a link between the patient and the batch of the product.

Suspicion of allergic or anaphylactic type reactions requires immediate discontinuation of the infusion. 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

The colloid-osmotic effect of human albumin 200 g/l is approximately four times that of blood plasma. Therefore, when concentrated albumin is administered, care must be taken to assure adequate hydration of the patient. Patients should be monitored carefully to guard against circulatory overload and hyperhydration. 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 "Dosage and Aministration") 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.

[CONTRAINDICATION]

Patients with history of hypersensitivity to this drug and its ingredients

[PRECAUTIONS]

1) Patient with cardiac disorders (Cardiac load could increase due to increased circulating plasma volume.)
2) Patient with excessive circulating plasma volume (Rapid infusions could cause circulatory disturbance such as cardiac overload and pulmonary edema.)
3) Patient with haemolytic or haemorrhagic anaemia (There is a possibility of human parvovirus B19 infection. In case of infection, acute systemic responses may occur along with fever and severe acute anaemia.
4) Immunodeficient or immunocompromised patient. (There is a possibility of human parvovirus B19 infection. In case of infection, prolonged anaemia may occur.)

[ADVERSE REACTIONS]

Mild reactions such as flush, urticaria, fever, and nausea occur rarely. These reactions normally disappear rapidly when the infusion rate is slowed down or the infusion is stopped. Very rarely, severe reactions such as shock may occur. In these cases, the infusion should be stopped and an appropriate treatment should be initiated.

[GENERAL CAUTIONS]

1) The patients should be closely monitored since the possibility of infection cannot be ruled out as it is difficult to completely inactivate or eliminate human Parvovirus B19, etc. in the plasma derivatives produced under the current manufacturing process.
2) When used for chronic diseases, it can cause a decrease in the ability of albumin synthesis. In particular, if concentration of serum albumin is more than 4g/dL, the synthesis of albumin may be inhibited, so careful treatment must be taken.
3) Due to the rapid increase in circulating plasma during infusion, the infusion rate must be adjusted and attention must be paid to pulmonary oedema and heart failure, etc. For the reference, 200 mL of circulating plasma volume is increased when 50 mL of albumin is administered.
4) The target concentration of 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 should be clearly identified and the serum albumin concentration and clinical improvement should be compared before and after administration. After administration, the effect should be monitored to determine whether to continue to be used, so as not to continue administration unnecessarily.

5) Along with the necessity of this drug in the treatment of the disease, it should also be explained to the patient that the risk of infection derived from human blood cannot be completely excluded, although certain safety measures are applied in the production process of this drug in order to prevent infection.
6) In case of hypoalbuminemia caused by chronic diseases such as liver cirrhosis, the concentration of serum albumin does not increase as expected since albumin passes into the extravascular spaces. In this case, caution must be taken since the decomposition of albumin is accelerated.

【INCOMPATIBILITIES】
In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products, except for 5% glucose or 0.9% sodium chloride.

【PREGNANCY】
The safety of Albumin SG 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.
No animal reproduction studies have been conducted with Albumin SG 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.

【PAEDIATRIC USE】
The safety of administration to low birth-weight infants and newborns has not been established.

【GERIATRIC USE】
Since the physiological function of the elderly is generally decreased, particular attention regarding the condition should be paid when treating the elderly.

【ATTENTION ON ADMINISTRATION】
1) Do not administer products containing insoluble matters or turbid products.
2) Infusion site must be chosen as far away from the infected or injured as possible.
3) This medicine must not be mixed with other medicines except for isotonic solution (e.g. 5% glucose or 0.9% sodium chloride).
4) Once opened, the drug product should be used immediately.
5) Do not use the remaining volume after administration as the remaining volume could be contaminated by bacteria. (This drug is a protein solution suitable for bacterial growth with no preservatives.)

【OTHERS】
This medicine does not include blood coagulation factors.

【PACKING UNIT】
50mL/vial, 100mL/vial Not all presentations may be available locally.

【SHELF-LIFE】
24 months from the manufacturing date.

【STORAGE CONDITION】
Keep the vial in the outer carton. Store at or below 30 °C. Do not freeze.

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Distributed by

HSA
Health Sciences Authority

11 Outram Road Singapore 169078

Manufactured by

SK plasma

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