GRIFOLS

Human Albumin Grifols® 20%

Solution for infusion

Composition

Active ingredient: Human albumin.

Solution containing 20% of protein of which at least 95% is human albumin.

Human Albumin Grifols® 20% has a hyperoncotic effect.

Excipients: Sodium caprylate, sodium N-acetyltryptophanate and water for injections.

Aluminium content ≤ 200 µg/l.

The solution contains between 130 - 160 mmol/l of sodium and not more than 2 mmol/l of potassium.

Pharmaceutical form and content

Solution for infusion.

Each 100 ml contains 20 g of human albumin.

Activity

Human Albumin Grifols® 20% is a sterile serum albumin solution derived from pooled venous blood plasma and obtained by fractionation according to Cohn's method with cold ethanol.

The product is pasteurised at 60 ºC for 10 hours.

Manufacturer

Instituto Grifols, S.A.

Can Guasch, 2 - Parets del Vallès

08150 Barcelona - SPAIN

Therapeutic indications

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

The choice of albumin rather than artificial colloid will depend on the clinical situation of the individual patient, based on official recommendations.

Contraindications

Hypersensitivity to albumin preparations or to any of the excipients.

Special precautions

If allergic or anaphylactic-type reactions occur, the infusion should be stopped immediately and appropriate treatment instituted. In case of shock, the current medical standards for shock-treatment should be observed.

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 20% 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.

20% Human albumin solutions are relatively low in electrolytes compared to the 4-5% human albumin solutions. When albumin is given, the electrolyte status of the patient should be monitored (see section Posology) 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 rate of infusion are not adjusted to the patients circulatory situation (see section Overdose). 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.

When medicinal products prepared from human blood or plasma are administered, infectious diseases due to transmission of infective agents cannot be totally excluded. This also applies to pathogens of unknown nature. The risk of transmission of infective agents is however reduced by:

- selection of donors by a medical interview and screening of individual donations and plasma pools for HBsAg and antibodies to HIV and HCV.
- testing of plasma pools for HCV genomic material.
- inactivation/removal procedures included in the production process that have been validated using model viruses. These procedures are considered effective for HIV, HCV, HAV and HBV.

The viral inactivation/removal procedures may be of limited value against non-enveloped viruses such as parvovirus B19 and other transmissible infectious agents.

Human Albumin Grifols® 20% manufactured to European Pharmacopoeia specifications by established processes has a reassuring viral safety record.

In the interest of patients, it is recommended that, whenever possible, every time that Human Albumin Grifols® 20% is administered to them, the name and batch number of the product is recorded.

The pediatric use of albumin has not been clinically evaluated. Therefore, physician should weigh the risks and benefits of the use of albumin in pediatric populations.

Interactions

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

Incompatibilities

Human Albumin Grifols® 20% must not be mixed with other medicinal products (except the recommended diluents), whole blood and packed red cells.

Warnings

Pregnancy and lactation

The safety of Human Albumin Grifols® 20% 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 Human Albumin Grifols® 20%.

Experimental animal studies are insufficient 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.

Effects on ability to drive

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

Posology

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

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 circulating volume and not plasma albumin levels should be used to determine the dose 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

This product is suitable for premature infants and dialysis patients.

Instructions for use

Human albumin 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).

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

The solution should be clear or slightly opalescent. 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 solution must be discarded appropriately even if refrigerated. Any unused product should be disposed of in accordance with local requirements.

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.

Undesirable effects

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.

For information on viral safety see Precautions.

If any adverse reaction, not enclosed in this item, appears, inform your physician or pharmacist.

Storage

Store at a temperature between 2 - 25 ºC.

Do not freeze.

Shelf-life

Human Albumin Grifols® 20% has a shelf-life of 3 years.

Sizes

Human Albumin Grifols® 20%:

Vials of 50 ml

Keep out of the reach and sight of children.

Revision of the text

8 March 2005