Albiomin 20%

1. NAME OF THE MEDICINAL PRODUCT

Albiomin 20% (200 g/l),
Solution for infusion

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Human albumin

Albiomin 20% is a solution containing 200 g/l of total protein of which at least 96% is human albumin.

Each vial of 50 ml contains 10 g of human plasma protein of which at least 96% is human albumin.
Each vial of 100 ml contains 20 g of human plasma protein of which at least 96% is human albumin.

The product has a hyperoncotic effect.

Produced from plasma from human donors.

Excipients with known effect:
One vial of 50 ml Albiomin 20% contains approximately 140 mg sodium (6.1 mmol).
One vial of 100 ml Albiomin 20% contains approximately 280 mg sodium (12.2 mmol).

For the full list of excipients, see 6.1.

3. PHARMACEUTICAL FORM

Solution for infusion.

A clear, slightly viscous liquid; it is almost colourless, yellow, amber or green.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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 or 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

Method of administration
Intravenous use
Human albumin can be directly administered by the intravenous route or it can also be diluted in an isotonic solution (e.g. 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

Hypersensitivity to albumin preparations or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Traceability
In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Transmissible agents
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 European Pharmacopoeia specifications by established processes.

Precautions for use
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 ensure 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 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 rate of infusion 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.

Sodium content

This medicinal product contains approximately 140 mg sodium (6.1 mmol) per 50 ml vial equivalent to 7.0% of the WHO recommended maximum daily intake of 2 g sodium for an adult. This medicinal product contains approximately 280 mg sodium (12.2 mmol) per 100 ml vial equivalent to 14.0% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

4.5 Interaction with other medicinal products and other forms of interaction

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

4.6 Fertility, pregnancy and lactation

Pregnancy

The safety of Albiomin 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 fetus and the neonate are to be expected.

Experimental animal studies are insufficient to assess the safety with respect to reproduction, development of the embryo or fetus, 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

Summary of the safety profile:

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.

Tabulated summary of adverse reactions:

The table presented below is according to the MedDRA system organ classification (SOC) and Preferred Term (PT) Level.
Frequencies have been evaluated according to the following convention: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1 000 to <1/100); rare (≥1/10 000 to <1/1 000); very rare (<1/10 000); not known (cannot be estimated from the available data)

The table represents the safety profile of Albiomin 20% (200 g/l) based on post-marketing experience. Since the reporting of adverse reactions is voluntary and the number of treated patients is unknown, an exact frequency cannot be estimated.

MedDRA System Organ Class (SOC)	Adverse Reaction	Frequency
Immune system disorders	Anaphylactic shock, anaphylactic reaction, bronchospasm, hypersensitivity	Not known
Cardiac disorders	Tachycardia	Not known
Vascular disorders	Shock, hypotension	Not known
Gastrointestinal disorders	Nausea	Not known
Skin and subcutaneous tissue disorders	Flushing, urticaria, pruritus, erythema, rash	Not known
General disorders and administration site conditions	Chills, pyrexia, application site extravasation	Not known
Investigations	Oxygen saturation decreased	Not known

For safety information with respect to transmissible agents, see 4.4.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form
https://sideeffects.health.gov.il

Additionally, you should also report to Kamada LTD to email address: pharmacovigilance@kamada.com

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.

Physiochemical data: Human albumin 200 g/l has a corresponding hyperoncotic effect.

The most important physiological functions of albumin result 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 situations 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

Human albumin is a normal constituent of the human plasma and acts like the 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-fetal toxicity, oncogenic or mutagenic potential.

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

N-acetyltryptophanate (16 mmol/l), sodium chloride (63 mmol/l), Sodium caprylate (16 mmol/l), water for injections.

6.2 Incompatibilities

Human albumin must not be mixed with other medicinal products (except those mentioned in section 6.6), whole blood and packed red blood cells.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.

Once the vial has been opened, the contents should be used immediately.

6.4 Special precautions for storage

Store below 25°C. Do not freeze.
Keep the vial in the outer carton in order to protect from light.

6.5 Nature and contents of container

50 ml or 100 ml of a solution in a vial (Type II glass) with a grey rubber stopper (bromobutyl) and a cap (aluminium) – pack size of one vial.

6.6 Special precautions for disposal and other handling

The solution can be directly administered by the intravenous route, or it can be diluted in an isotonic solution (e.g. 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.

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.

Any unused product should be disposed of in accordance with local requirements.

7. MANUFACTURER

Biotest Pharma GmbH, Landsteinerstrasse 5, 63303 Dreieich, Germany

8. LICENSE HOLDER

Kamada Ltd., Beit Kama, Israel

LICENSE NUMBER
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