

2½"
63.5mm

19"
482.6mm

4.6. Pregnancy and lactation

The safety of Albutein® 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 Albutein® 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.

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

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 safety 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. To report SUSPECTED ADVERSE REACTIONS, contact Grifols at 1-323-225-2221.

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.

Physico-chemical data: human albumin 200 g/l has a corresponding hyperoncotic effect.

The most important physiological function 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

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

Each ml contains:

Sodium chloride (q.s. sodium ion)	0.145 mmol
Sodium caprylate	0.016 mmol
Sodium N-acetyltryptophanate	0.016 mmol
Water for injections q.s.	1 mL

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

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 cells.

6.3. Shelf-life

3 years.

6.4. Special precautions for storage

Do not store above 30 °C. Do not freeze.

Keep the vial in the outer carton in order to protect from light.

6.5. Nature and contents of container

Albutein® 20% is supplied in clear type II glass vials closed with butyl rubber stoppers. Each vial contains 50 ml or 100 ml of human albumin.

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.

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 product or waste material should be disposed of in accordance with local requirements.

7. MANUFACTURER AND PRODUCT REGISTRATION HOLDER

Manufacturer

Grifols Biologicals LLC
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USA

Product Registration Holder

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8. MARKETING AUTHORISATION NUMBER(S)

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