

Package leaflet: Information for the user

Albuman 40 g/l solution for infusion

Albuman 200 g/l solution for infusion

Human albumin

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Albuman is and what it is used for
2. What you need to know before you use Albuman
3. How to use Albuman
4. Possible side effects
5. How to store Albuman
6. Contents of the pack and other information

1. What Albuman is and what it is used for

Albuman contains the human protein albumin. Human albumin is a normal constituent of human plasma and acts like albumin present in your body when given as a replacement therapy. Albumin stabilises circulating blood volume and is a carrier of hormones, enzymes, medicinal products and toxins.

Albumin is used for restoration and maintenance of circulating blood volume in your body where volume deficiency has been demonstrated and your doctor considers replacement therapy appropriate.

2. What you need to know before you use Albuman

Do not use Albuman:

- if you are allergic to human albumin or any of the other ingredients of this medicine (listed in section 6).

Warning and precautions

Talk to your doctor or pharmacist before using Albuman.

Take special care with Albuman, if you are suffering from any of the following diseases:

- decompensated cardiac insufficiency
- hypertension
- heart, liver or kidney diseases or if you use drugs that increase the vasopressin effect
- oesophageal varices
- pulmonary oedema

- tendency to bleedings
- severe anaemia
- anuria due to e.g. renal impairment.

Your blood electrolytes may need to be monitored. This is especially the case if you use drugs that increase the vasopressin effect, see below: Other medicines and Albuman.

When medicines are made from human blood or plasma, certain measures are put in place to prevent infections being passed on to patients. These include careful selection of blood and plasma donors to make sure those at risk of carrying infections are excluded, and the testing of each donation and pools of plasma for signs of virus/infections. Manufacturers of these products also include steps in the processing of the blood or plasma that can inactivate or remove viruses. Despite these measures, when medicines prepared from human blood or plasma are administered, the possibility of passing on infection cannot be totally excluded. This also applies to any unknown or emerging viruses or other types of infections.

There are no reports of virus infections with albumin manufactured to European Pharmacopoeia specifications by established processes, such as with Albuman.

It is strongly recommended that every time you receive a dose of Albuman the name and batch number of the product are recorded in order to maintain a record of the batches used.

Other medicines and Albuman

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines. This is especially important if you use drugs that increase the vasopressin effect or otherwise increase the risk of hyponatraemia, such as diuretics, non-steroidal anti-inflammatory drugs (NSAIDs), antipsychotics, selective serotonin reuptake inhibitors, narcotics and antiepileptics.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

Albumin has no harmful effects on ability to drive and use machines.

Important information about some of the ingredients of Albuman

This medicinal product contains sodium, the concentration of which is:

- in Albuman 40 g/l 140 mmol per litre (3.2 g/l).
- in Albuman 200 g/l 100 mmol per litre (2.3 g/l).

To be taken into consideration by patients on a controlled sodium diet.

3. How to use Albuman

Albuman will be given as a slow infusion. A doctor or a nurse will administer the solution into your vein through an infusion set. The dose and infusion rate will be adjusted to your individual requirements by your doctor. The dose required depends on your length and weight, the severity of your condition and on your continuing fluid and protein losses.

Albuman 40 g/l is directly administered by the intravenous route. Albuman 200 g/l can be administered directly or it can also be diluted in an isotonic solution (e.g. 5% glucose or 0.9%

sodium chloride). However, it must not be diluted with water for injections as this may cause haemolysis in recipients.

Albumin must not be mixed with other medicinal products, whole blood and packed red cells. During the infusion your blood pressure, heart function, blood count and breathing will be checked regularly in order to ascertain that your dosage is appropriate.

If you use more Albuman than you should

Hypervolaemia may occur if you are given overdose. The signs are e.g. headache, dyspnoea and increased blood pressure. Should these signs occur, the infusion will be stopped immediately. You may be given treatment to remove the excess fluid.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Rare side effects, which occur in 1-10 out of 10 000 treated patients:

Flush, urticaria, fever and nausea.

These reactions normally disappear rapidly when the infusion rate is slowed down or the infusion is stopped.

Very rare side effects, which occur in less than 1 out of 10 000 treated patients:

anaphylactoid reactions such as shock.

In these cases, the infusion will be stopped and an appropriate treatment will be initiated.

Not known: frequency cannot be estimated from the available data

Hyponatraemia (low sodium concentration in blood)

Acute hyponatraemic encephalopathy (cerebral oedema)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Albuman

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the package.

Albuman 40 g/l

Store below 25°C.

Do not freeze. Store in the original package in order to protect from light.

Albuman 200 g/l

10 ml pack size: Store in a refrigerator (2°C – 8°C). 50 ml and 100 ml pack size: Store below 25°C.

Do not freeze. Store in the original package in order to protect from light.

Do not use Albuman if you notice that the solution is cloudy or has deposits. This may indicate that albumin is unstable or that the solution has become contaminated.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Albuman contains

Albuman 40 g/l

- The active substance is human albumin 40 g/l; in vial of 4 g/100 ml or 10 g/250 ml or 16 g/400 ml
- The other ingredients are sodium caprylate, sodium chloride, sodium hydroxide or hydrochloric acid and water for injections.

Albuman 200 g/l

- The active substance is human albumin 200 g/l; in vial of 2 g/10 ml or 10 g/50 ml or 20 g/100 ml
- The other ingredients are sodium caprylate, sodium chloride, sodium hydroxide or hydrochloric acid and water for injections.

What Albuman looks like and contents of the pack

Albuman 40 g/l

Albuman 40 g/l is presented as a solution for infusion in a vial (100 ml or 250 ml or 400 ml – pack size of 1).

The solution is clear, slightly viscous; it is almost colourless, yellow, amber or green.

Not all pack sizes may be marketed.

Albuman 200 g/l

Albuman 200 g/l is presented as a solution for infusion in a vial (10 ml or 50 ml or 100 ml – pack size of 1).

The solution is clear, slightly viscous; it is almost colourless, yellow, amber or green.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Sanquin Plasma Products B.V.
Plesmanlaan 125
NL-1066 CX Amsterdam
The Netherlands
Tel.: +31 20 512 3355

This medicinal product is authorized in the Member States of the EEA under the following names:

Finland Albuman 40 g/l and Albuman 200 g/l

Netherlands	Albuman 40 g/l and Albuman 200 g/l
Iceland	Albuman 40 g/l and Albuman 200 g/l
Denmark	Crealb 40 g/l and Crealb 200 g/l
Estonia	Crealb 40 g/l and Crealb 200 g/l
Norway	Crealb 40 g/l and Crealb 200 g/l
Sweden	Crealb 40 g/l and Crealb 200 g/l

This leaflet was last revised on 14.06.2019

Detailed information on this medicine is available on the web site of National Agency for Medicines.

The following information is intended for health care professionals only:

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 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

Fluid balance, serum electrolytes and acid-base balance may need to be monitored before and during administration. Particular attention to serum sodium should be paid in patients with increased non-osmotic vasopressin release (syndrome of inappropriate antidiuretic hormone secretion, SIADH) and in patients co-medicated with vasopressin agonist drugs, due to the risk of hospital acquired hyponatraemia. Albuman 200 g/l is slightly hypotonic. Monitoring of serum sodium is particularly important for hypotonic fluids.

Paediatric population

Data on the use of Albuman in children and adolescents (0-18 years) are limited; therefore, the product should only be administered to these individuals if the benefits clearly outweigh potential risks. The posology in children and adolescents should be adjusted to the patient's individual requirements.

The infusion rate and volume depend on age, weight, clinical condition (e.g., burns, surgery, head injury, infections), and concomitant therapy should be determined by the consulting physician experienced in paediatric intravenous fluid therapy.

Method of administration

Albuman 40 g/l solution can be directly administered by the intravenous route.

Albuman 200 g/l 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).

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.

For more information on method of administration, see section 3 of this package leaflet.

Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

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

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

If comparatively large volumes of albumin solution 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. 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 should be stopped immediately.

Albuman 40 g/l contains 140 mmol/l of sodium (3.2 g/l)

Albuman 200 g/l contains 100 mmol/l of sodium (2.3 g/l)

To be taken into consideration by patients on a controlled sodium diet.

High volume infusion must be used under specific monitoring in patients with cardiac or pulmonary failure, and in patients with non-osmotic vasopressin release (including SIADH), due to the risk of hospital-acquired hyponatraemia (see below).

Hyponatraemia

Patients with non-osmotic vasopressin release (e.g. in acute illness, pain, post-operative stress, infections, burns and central nervous system diseases), patients with heart, liver and kidney disease, patients exposed to vasopressin agonists and other drugs that can lower serum sodium are at particular risk of acute hyponatraemia. Acute hyponatraemia can lead to acute hyponatraemic encephalopathy (cerebral oedema) characterized by headache, nausea, seizures, lethargy and vomiting. Patients with cerebral oedema are at particular risk of severe, irreversible and life-threatening brain injury. Children, women in the fertile age and patients with reduced cerebral compliance (e.g. meningitis, intracranial bleeding, cerebral contusion and brain oedema) are at particular risk of life threatening brain swelling due to hyponatraemia.

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 transmission with albumin manufactured to European Pharmacopoeia specifications by established processes.

It is strongly recommended that every time that Albuman 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.

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.

Incompatibilities

This medicinal product must not be mixed with other medicinal products, whole blood and packed red cells. Except Albuman 200 g/l can be diluted in an isotonic solution (e.g. 5% glucose or 0.9% sodium chloride).