Package leaflet: Information for the user

Albuman 40 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.
- 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 40 g/l is and what it is used for

Albuman 40 g/l contains the human protein albumin. Human albumin is a natural component of human plasma and functions similarly to the albumin present in your body when administered. Albumin stabilises circulating blood volume and is a carrier of hormones, enzymes, medicinal products and toxins.

Albumin is used to restore and maintain circulating blood volume where volume deficiency has been demonstrated, and your doctor will determine if you need this medicine. This depends on your clinical condition.

2. What you need to know before you use Albuman 40 g/l

Do not use Albuman 40 g/l:
- if you are allergic to human albumin or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before using this medicine.

Take special care with Albuman 40 g/l if you are suffering from any of the following conditions:
- decompensated cardiac insufficiency
- hypertension
- oesophageal varices
- pulmonary oedema
- tendency to bleedings
- severe anaemia

- anuria due to e.g. renal impairment.

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,
- the testing of each donation and pools of plasma for signs of virus/infections,
- the inclusion of 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 requirements by established processes.

It is strongly recommended that every time you receive a dose of Albuman 40 g/l the name and batch number of the medicine are recorded in order to maintain a record of the batches used.

Other medicines and Albuman 40 g/l
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

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 40 g/l
This medicine contains sodium (main component of cooking /table salt):

One vial of 100 ml Albuman 40 g/l contains 320 mg sodium. This is equivalent 16% of the recommended maximum daily dietary intake of sodium for an adult.

One vial of 250 ml Albuman 40 g/l contains 800 mg sodium. This is equivalent 40% of the recommended maximum daily dietary intake of sodium for an adult.

One vial of 400 ml Albuman 40 g/l contains 1280 mg sodium. This is equivalent 64% of the recommended maximum daily dietary intake of sodium for an adult.

Patients on a controlled sodium diet should take this into consideration.

3. How to use Albuman 40 g/l

Albuman 40 g/l 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.

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 40 g/l 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 must 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 must be stopped and an appropriate treatment will be initiated.

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 Dutch pharmacovigilance centre LAREB, Website www.lareb.nl>. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Albuman 40 g/l

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 carton and vial label after EXP. The expiry date refers to the last day of that month.

Store below 25 °C. Do not freeze.
Store in the original package in order to protect from light.

After first opening: the product should be used immediately.

Do not use this medicine 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 40 g/l contains

- The active substance is human albumin. One liter of solution contains 40 g of total protein, of which at least 95% is human albumin.
- The other ingredients are sodium caprylate, sodium chloride, sodium hydroxide or hydrochloric acid and water for injections.
  Total amount of sodium ions: 140 mmol/l (see Section 2).

What Albuman 40 g/l looks like and contents of the pack

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 one vial).
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

Prothya Biosolutions Netherlands B.V.
Plesmanlaan 125
NL-1066 CX Amsterdam
The Netherlands

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

Finland, the Netherlands: Albuman 40 g/l

This leaflet was last revised in February 2025.

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

The following information is intended for healthcare 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.

<u>Posology</u>

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

Paediatric population

Data on the use of Albuman 40 g/l 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.

Method of administration

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

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 of this package leaflet.

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.

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

200-250 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 and appropriate steps taken to restore or maintain electrolyte balance.

Albumin solutions must not be diluted with water for injections as this may cause haemolysis in recipients.

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 is to be stopped immediately.

Special warning about excipients
This medicinal product contains 140 mmol/l of sodium (3.2 g/l):

320 mg sodium per vial of 100 ml, equivalent to 16% of the WHO recommended maximum daily dietary intake of 2 g sodium for an adult.

800 mg sodium per vial of 250 ml, equivalent to 40% of the WHO recommended maximum daily dietary intake of 2 g sodium for an adult.

1280 mg sodium per vial of 400 ml, equivalent to 64% of the WHO recommended maximum daily dietary intake of 2 g sodium for an adult.

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

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

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 is to be stopped immediately and the patient’s haemodynamic parameters carefully monitored.

Incompatibilities
Human albumin must not be mixed with other medicinal products, whole blood and packed red cells.