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

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
- 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, 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.

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 medicine contains sodium (main component 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 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 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 intake of sodium for an adult.

One vial of 50 ml Albuman 200 g/l contains 115 mg sodium. This is equivalent of 6 % of the recommended maximum daily intake of sodium for an adult.

One vial of 100 ml Albuman 200 g/l contains 230 mg sodium. This is equivalent of 12 % of the recommended maximum daily intake of sodium for an adult.

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.

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 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

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 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.

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 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 (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

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	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
Cyprus	Albuman 40 g/l and Albuman 200 g/l

Sweden	Crealb 40 g/l and Crealb 200 g/l
Austria	Crealb 40 g/l and Crealb 200 g/l
Germany	Crealb 40 g/l and Crealb 200 g/l
Poland	Crealb 40 g/l and Crealb 200 g/l
Slovakia	Crealb 40 g/l and Crealb 200 g/l

This leaflet was last revised in October 2021

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:

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