Package leaflet: Information for the user

Human Albumin Biotest 5%, solution for infusion
Human albumin

Read this entire 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 Human Albumin Biotest 5% is and what it is used for
2. What you need to know before you are given Human Albumin Biotest 5%
3. How you are given Human Albumin Biotest 5%
4. Possible side effects
5. How to store Human Albumin Biotest 5%
6. Contents of the pack and other information

1. What Human Albumin Biotest 5% is and what it is used for

Human Albumin Biotest 5% is a solution for infusion (into a vein). 1000 ml solution contains 50 g human plasma protein of which at least 95% is human albumin.

Human Albumin Biotest 5% is used to restore and maintain circulating blood volume where there is a low blood volume and the use of a colloid, such as albumin, is required.

2. What you need to know before you are given Human Albumin Biotest 5%

You will not receive Human Albumin Biotest 5% if:
- you are allergic to albumin preparations or to any of the other ingredients of this medicine (listed in section 6).

Human Albumin Biotest 5% Warnings and precautions
Suspicion of allergic or anaphylactic type reactions requires an immediate stop of the injection. In case of shock, standard medical treatment for shock should be applied.

The infusion will also be stopped if you develop any of the following conditions as a sign of cardiovascular overload (hypervolaemia):
- headache
- dyspnoea (difficulties in breathing)
- jugular vein congestion (a build up of fluid in a neck vein)
- increased blood pressure
- raised venous pressure (increased pressure in the veins)
- pulmonary oedema (water on the lungs)

You should tell your doctor if you suffer from any of the following conditions:
- Decompensated cardiac insufficiency (heart failure)
- Hypertension (high blood pressure)
• Oesophageal varices (enlarged veins in the gullet)
• Pulmonary oedema (water on the lungs)
• Haemorrhagic diathesis (tendency to abnormal or spontaneous bleeding)
• Severe anaemia (reduced red blood cells)
• Renal and post-renal anuria (decreased or absent urine production)

He/She will take the appropriate precautions. You will also be monitored by your doctor to check your circulatory situation with the electrolyte balance and blood volume.

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.

It is strongly recommended that every time you receive a dose of Human Albumin Biotest 5% the name and batch number of the product are recorded in order to maintain a record of the batches used.

**Other medicines and Human Albumin Biotest 5%**
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

**Pregnancy and breast-feeding**
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. If you have already told your doctor then follow any instructions that may have been given to you.

**Driving and using machines**
Human Albumin Biotest 5% has no known effects on the ability to drive or use machines.

**Human Albumin Biotest 5% contains sodium**
This medicinal product contains 145 mmol sodium per litre. To be taken into consideration by patients on a controlled sodium diet.

### 3. How you are given Human Albumin Biotest 5%
Human Albumin Biotest 5% treatment will usually be given in hospital by a doctor or a nurse. Human albumin can be given directly into a vein.

**Dosage and Frequency of Administration**
The amount of Human Albumin Biotest 5% you receive depends on your size, the illness, and on fluid or protein losses.

Your doctor will calculate the dose of Human Albumin Biotest 5% and how often you will receive it to obtain the correct levels in your blood.

**If you are given more Human Albumin Biotest 5% than you should**
This is very unlikely but your doctor will know what to do if this happens.

If you have any further questions on the use of the medicine, ask your doctor or pharmacist.
4. Possible side effects

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

The following side effects have been reported:

- flush,
- urticaria (nettle rash),
- fever and nausea (feeling sick).

These occur rarely.

Very rarely, severe reactions such as shock may occur. If this happens the infusion will be stopped and the appropriate treatment will be started.

**Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme. Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard)

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Human Albumin Biotest 5%

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

Do not use this medicine after the expiry date which is stated on label and outer carton.

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

Do not store above 25ºC.

**Do not freeze.**

The product, once opened, should be used immediately.

Immediately before administration, check that the solution is clear. The product must not be used if any cloudiness or particles are visible.

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 Human Albumin Biotest 5% contains**

Each vial with 250 ml solution contains 12.5 g of human plasma protein of which at least 95% is human albumin.

The other ingredients are: sodium caprylate (4 mmol/l), sodium chloride (130 mmol/l), N-acetyltryptophanate (4 mmol/l), water for injections.

**What Human Albumin Biotest 5% looks like and contents of the pack**

A clear, slightly viscous liquid; it is almost colourless, yellow, amber or green.
Glass vial with 250 ml

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PL 04500/0011

This medicinal product is authorised in the Member States of the EU under the following trade names:

- Austria: Albiomin 50 g/l
- Denmark: Human Albumin Biotest 50 g/l
- Germany: Albiomin 5% (50 g/l)
- Hungary: Human Albumin 5% Biotest oldatos infúzió
- Italy: Albiomin 5% (50 g/l)
- Romania: Albiomin 50 g/l
- United Kingdom: Human Albumin Biotest 5%

This leaflet was last revised in 08/2015.

THE FOLLOWING INFORMATION IS INTENDED FOR MEDICAL OR HEALTHCARE PROFESSIONALS ONLY:

Special warnings and special precautions for use
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.
There are no reports of virus infections with albumin manufactured to European Pharmacopoeia specifications by established processes.

It is strongly recommended that every time a dose of Human Albumin Biotest 5% is administered the name and batch number of the product are recorded in order to maintain a record of the batches used.

Interactions with other medicinal products and other forms of interactions
No specific interactions of human albumin with other products are known.

Posology and method of administration
Posology
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**
In plasma exchange the infusion-rate should be adjusted to the rate of removal.

**Notes for handling**
The solution can be directly administered by the intravenous route.

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 should be disposed of in accordance with local requirements.