

Package leaflet: Information for the user**Human Albumin Biotest 20%, 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 nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Human Albumin Biotest 20% is and what it is used for
2. What you need to know before you use Human Albumin Biotest 20%
3. How to use Human Albumin Biotest 20%
4. Possible side effects
5. How to store Human Albumin Biotest 20%
6. Contents of the pack and other information

1. What Human Albumin Biotest 20% is and what it is used for

Human Albumin Biotest 20% is a solution for infusion (into a vein). One litre solution contains 200 g human plasma protein of which at least 96% is human albumin.

Human Albumin Biotest 20% 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 use Human Albumin Biotest 20%**Do not use Human Albumin Biotest 20%:**

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

Warnings and precautions

Suspicion of allergic or anaphylactic type reactions requires an immediate stop of the infusion. 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)

Talk to your doctor if you suffer from any of the following conditions:

- heart failure (decompensated cardiac insufficiency)
- high blood pressure (hypertension)
- enlarged veins in the gullet (oesophageal varices)
- water on the lungs (pulmonary oedema)

- tendency to abnormal or spontaneous bleeding (haemorrhagic diathesis)
- reduced red blood cells (severe anaemia)
- decreased or absent urine production (renal and post-renal anuria)

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.

Information on transmission of infectious agents

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 Human Albumin Biotest 20% 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 20%

Tell your doctor 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 for advice before taking this medicine. Your doctor will decide if Human Albumin Biotest 20% may be used during pregnancy and breast-feeding.

Driving and using machines

Human Albumin Biotest 20% has no known effects on the ability to drive or use machines.

Human Albumin Biotest 20% contains sodium

This medicinal product contains approximately 140 mg sodium (main component of cooking/table salt) per 50 ml vial. This is equivalent to 7.0% of the recommended maximum daily dietary intake of sodium for an adult.

This medicinal product contains approximately 280 mg sodium (main component of cooking/table salt) per 100 ml vial. This is equivalent to 14.0% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use Human Albumin Biotest 20%

Human Albumin Biotest 20% treatment will usually be given in hospital by a doctor or a nurse. Human albumin can be given directly into a vein or diluted in 0.9% sodium chloride.

Dosage and Frequency of Administration

The amount of Human Albumin Biotest 20% you receive depends on your size, the illness, and on fluid or protein losses.

Your doctor will calculate the dose of Human Albumin Biotest 20% and how often you will receive it to obtain the correct levels in your blood.

If you use more Human Albumin Biotest 20% 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 this medicine, ask your doctor or nurse.

4. Possible side effects

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

If you notice any of the following effects, tell your doctor immediately:

- rash
- itching
- wheezing
- difficulty breathing
- swelling of the eyelids, face, lips, throat or tongue
- extremely low blood pressure with symptoms like dizziness, confusion, fainting, fast pulse

This can be an allergic or in rare cases a serious allergic reaction (anaphylactic shock) or a hypersensitivity reaction.

The following side effects have been reported for Human Albumin Biotest 20% or are known from other human albumin products:

Not known (frequency cannot be estimated from the available data):

- Hypersensitivity, anaphylactic reaction, anaphylactic shock
- Tightening of the lung (bronchospasm)
- Increased heart rate (tachycardia)
- Shock
- Nausea
- Skin reactions (flushing, urticaria, pruritus, erythema, rash)
- Chills
- Fever
- Low blood pressure (hypotension)
- Reduced oxygen saturation
- Leakage at the injection site (extravasation)

Reporting of side effects

If you get any side effects, talk to your doctor 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 or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Human Albumin Biotest 20%

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

Do not store above 25°C.

Do not freeze.

Once opened, the product 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 20% contains

Each vial with 50 ml solution contains 10 g of human plasma protein of which at least 96% is human albumin.

Each vial with 100 ml solution contains 20 g of human plasma protein of which at least 96% is human albumin.

The other ingredients are: sodium caprylate (16 mmol/l), sodium chloride (63 mmol/l), N-acetyltrypthophanate (16 mmol/l), water for injections.

What Human Albumin Biotest 20% looks like and contents of the pack

A clear, slightly viscous liquid; it is almost colourless, yellow, amber or green.

Glass vial with 50 ml

Glass vial with 100 ml

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THE FOLLOWING INFORMATION IS INTENDED FOR HEALTHCARE PROFESSIONALS ONLY:

Special warnings and precautions for use

The colloid-osmotic effect of human albumin 200 g/l is approximately four times that of blood plasma. Therefore, when concentrated albumin is administered, care must be taken to ensure adequate hydration of the patient. Patients should be monitored carefully to guard against circulatory overload and hyperhydration.

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.

Interaction with other medicinal products and other forms of interaction

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**Intravenous use**

Human albumin can be directly administered by the intravenous route or it can be diluted in an isotonic solution (e.g. 0.9% sodium chloride).

In plasma exchange the infusion rate should be adjusted to the rate of removal.

Notes for handling

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 vial has been opened, the contents should be used immediately. Any unused product should be disposed of in accordance with local requirements.