CSL Behring

Package leaflet: Information for the user

Alburex® 5, 50 g/l, solution for infusion &
Alburex® 20, 200 g/l, solution for infusion
Human albumin

Read all of this leaflet carefully before you are given 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 healthcare professional.
- If you get any side effects, talk to your doctor or healthcare professional. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What Alburex is and what it is used for

What Alburex is
Alburex is a plasma substitute.

How Alburex works
Albumin stabilises the circulating blood volume. It is a carrier of hormones, enzymes, medicines and toxins. The albumin protein in Alburex is isolated from human blood plasma. Therefore the albumin works exactly as if it was your own protein.

What Alburex is used for
Alburex is used to restore and stabilise the circulating blood volume. It is normally used under intensive care situations, when your blood volume has decreased critically. This may be the case e.g.:
- due to severe loss of blood after an injury, *or*
- due to a large surface burn

The choice of using Alburex will be made by your doctor. It will depend on your individual clinical situation.

2. What you need to know before you are given Alburex

➔ Read this section carefully. The information given should be taken into consideration by you and your doctor before you are given Alburex.

Do NOT use Alburex

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

Warnings and precautions

➔ Talk to your doctor or healthcare professional before you are given Alburex.

Which circumstances increase the risk of having side effects?

Your doctor or healthcare professional will take special care if an abnormal increase in blood volume (hypervolaemia) or blood dilution (haemodilution) could be dangerous for you. Examples of such conditions are:

- heart insufficiency which needs to be treated with medicines (decompensated cardiac insufficiency)
- high blood pressure (hypertension)
- expansion of the gullet vein (oesophageal varices)
- abnormal accumulation of liquid in the lung (pulmonary oedema)
- predisposition for bleeding (haemorrhagic diathesis)
- severe decrease of red blood cells (severe anaemia)
- severe decrease of urine excretion because of renal impairment or outflow impairment (renal and post-renal anuria)

➔ Tell your doctor or healthcare professional before treatment if at least one of these conditions applies to you.

When stopping the infusion may be required?

- Allergic reactions (hypersensitivity reactions) may occur and may very rarely be severe enough to cause shock (see also section 4 'Possible side effects').

➔ Tell your doctor or healthcare professional immediately if you notice such reactions during the infusion of Alburex. He or she will decide to stop the infusion completely and start the appropriate treatment.

- An abnormal increase in blood volume (hypervolaemia) may occur if the dosage and infusion rate are not adequately adjusted to your condition. This may lead to an overload of the heart and circulatory system (cardiovascular overload). First signs of such an overload are headache, breathing difficulty or swelling of your neck veins (jugular vein congestion).

➔ Tell your doctor or healthcare professional immediately if you notice such signs. He or she will stop the infusion and monitor your circulation as necessary.

Information on safety with respect to infections

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 and 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 are given a dose of Alburex the name and batch number of the product are recorded, in order to maintain a record of the batches used.

Other medicines and Alburex
No specific interactions of Alburex with other medicines are known.
➔ However, always tell your doctor or healthcare professional before treatment if you are taking, have recently taken or might take any other medicines.

Pregnancy, breast-feeding and fertility
➔ Tell your doctor or healthcare professional if you are pregnant, plan to become pregnant or are breast-feeding. Your doctor will decide whether you can receive Alburex during your pregnancy or while you are breast-feeding.

The use of Alburex in pregnant or breast-feeding women has not been studied separately. Nevertheless, medicines containing human albumin have been used in pregnant or breast-feeding women. The experience showed that no harmful effects on the course of pregnancy, or on the foetus and the newborn are to be expected.

Driving and using machines
No effects of Alburex on the ability to drive and use machines have been observed.

Alburex contains sodium
This medicine contains approximately 3.2 mg sodium per ml of solution (140 mmol/l).
Your doctor or healthcare professional will take that into consideration if you are on a controlled sodium diet.

3. How to use Alburex

Alburex is given to you by your doctor or healthcare professional.
It is intended only for infusion into your veins (intravenous infusion). The product should be warmed to room or body temperature before it is given.

Your doctor decides how much Alburex you will receive. The amount and infusion rate depends on your individual requirements.
Your doctor or healthcare professional will regularly monitor important blood flow values like:

- your blood pressure,
- your pulse rate,
- your urine output,
- your blood tests.

These values are monitored to determine the right dose and infusion rate.

Alburex 5 must not be mixed with other medicinal products or blood-derived products.
Alburex 20 must not be mixed with other medicinal products (except dilution solvents such as 5% glucose and 0.9% sodium chloride) and blood-derived products.

If you are given more Alburex than you should
Alburex is administered under medical supervision only. An overdosage is therefore very unlikely to occur. An abnormal increase in blood volume (hypervolaemia) may occur if the dosage and infusion rate are too high. This may lead to an overload of the heart and circulatory system (cardiovascular overload).

First signs of such an overload include:

- headache,
- breathing difficulty,
- swelling of your neck veins (jugular vein congestion).

➔ Tell your doctor or healthcare professional immediately if you notice such symptoms.

Your doctor or healthcare professional may also detect signs like

- an increased blood pressure,
- a raised central venous pressure,
- an abnormal accumulation of liquid in the lung (pulmonary oedema).

In all these cases, he or she will stop the infusion and monitor your circulation as necessary.

4. Possible side effects

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

Such side effects may occur even when you have previously received Alburex and had tolerated it well.

General experience with human albumin solutions showed that the following side effects may be observed.

Allergic reactions (hypersensitivity reactions) may occur and may **very rarely** (less than *1 in 10,000* persons treated) be severe enough to cause shock.

Symptoms of an allergic reaction may include any, some or many of the following:

- skin reactions, e.g. redness, itching, swelling, blistering, rash or hives (itchy bumps)
- difficulty breathing, e.g. wheezing, chest tightness, shortness of breath or cough
- swelling of the face, eyelids, lips, tongue or throat
- cold-like symptoms, e.g. stuffy or runny nose, sneezing, red, itchy, swollen or watery eyes
- headache, stomach ache, nausea, vomiting or diarrhoea.

➔ Tell your doctor or healthcare professional immediately if you notice such reactions during the infusion of Alburex. In this case, he or she will stop the infusion and start the appropriate treatment.

The following mild side effects may occur **rarely** (between *1 in 1,000* and *1 in 10,000* persons treated):

- flushing
- itchy rash (urticaria)
- fever
- nausea

They will normally disappear rapidly when the infusion is slowed down or the infusion is stopped.

The same side effects have been observed with Alburex since the product is on the market. However, the exact frequency of these side effects is not known.

Reporting of side effects
If you get any side effects, talk to your doctor or healthcare professional. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

UK:
Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

Ireland:
HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
Email: medsafety@hpra.ie

Malta:
ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal

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

5. How to store Alburex

- 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 outer carton and the vial label after the abbreviation «EXP». The expiry date refers to the last day of that month.
- Once the vial has been opened, the contents should be used immediately.
- Do not store above 25 °C.
- Do not freeze.
- Keep the vial in the outer carton in order to protect from light.
- Do not use this medicine if you notice that the solution is cloudy or has particles.
- 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 Alburex contains

- The **active substance** is human albumin.

  Alburex 5 is a solution containing 50 g/l of total protein, of which at least 96% is human albumin.
  One vial of 100 ml containing 5 g of human albumin.
  One vial of 250 ml containing 12.5 g of human albumin.
  One vial of 500 ml containing 25 g of human albumin.

  Alburex 20 is a solution containing 200 g/l of total protein, of which at least 96% is human albumin.
  One vial of 50 ml contains 10 g of human albumin.
  One vial of 100 ml contains 20 g of human albumin.

- The **other ingredients** are sodium N-acetyltryptophanate, sodium caprylate, sodium chloride, and water for injections.

What Alburex looks like and contents of the pack

Alburex is a solution for infusion. The solution is clear and slightly viscous. It may be almost colourless or yellow, amber or green.

Pack sizes:
Alburex 5: 1 vial per pack (5 g/100 ml, 12.5 g/250 ml, 25 g/500 ml)
Alburex 20: 1 vial per pack (10 g/50 ml, 20 g/100 ml)

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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