GRIFOLS

Package Leaflet: Information for the User

Albutein® 50 g/l
Solution for infusion

HUMAN ALBUMIN

Read all of this leaflet carefully before you start using this medicine.

- 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 symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT ALBUTEIN® 50 g/l IS AND WHAT IT IS USED FOR

Albutein® 50 g/l is a solution for intravenous infusion containing proteins extracted from human plasma, which is the liquid part of the blood. Each bottle contains a solution of 50 g plasma protein/litre of which at least 95% is human albumin protein.

This medicinal product belongs to a group of medicines known as plasma substitutes and plasma protein fractions.

Albutein® 50 g/l is used to restore and maintain the circulating blood volume where volume deficiency has been demonstrated, and use of a plasma substitute is appropriate. The choice of an albumin solution rather than an artificial plasma substitute will depend on the clinical situation of the individual patient, based on official recommendations.

If you have any questions about the use of Albutein® 50 g/l please ask your doctor.

2. BEFORE YOU USE ALBUTEIN® 50 g/l

Do not use Albutein® 50 g/l

If you are allergic (hypersensitive) to human albumin protein or to any of the other ingredients (see Important information about some of the ingredients of Albutein® 50 g/l at the end of this section).

Take special care with Albutein® 50 g/l

- If you think you are suffering from an allergic reaction with breathing difficulties, feeling weak or any other symptoms, the infusion must be stopped immediately.
- Tell your doctor if you think you are suffering from any of the following conditions:
  - A weak heart
  - High blood pressure
  - Oesophageal varices (enlarged veins in the oesophagus)
  - Pulmonary oedema (liquid accumulation in the lungs)
  - Bleeding or blood clotting disorders
  - Severe anaemia (absence of red blood cells)
  - Problems with urine production

These conditions may rule out the use of Albutein® 50 g/l in your treatment, or cause the doctor to modify the dosage/infusion rate to avoid complications.

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 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 Albutein® 50 g/l the name and batch number of the product are recorded in order to maintain a record of all batches that have been used.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

No specific interactions of human albumin with other medicines are known.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

If you are pregnant or breast-feeding you must tell your doctor who will decide if Albutein® 50 g/l can be used.

Driving and using machines

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

Important information about some of the ingredients of Albutein® 50 g/l

Patients on a controlled sodium diet should take into consideration that this medicine contains 833.8 mg (36.3 mmol) sodium per vial of 250 ml and 1667.5 mg (72.5 mmol) sodium per vial of 500 ml.

This medicine contains very low levels of potassium.

3. HOW TO USE ALBUTEIN® 50 g/l

Albutein® 50 g/l is a product intended for hospital administration only. It will be administered as an intravenous infusion by medical staff and must not be self administered.

The dosage and the infusion rate of Albutein® 50 g/l you receive, as well as the frequency and duration of your treatment, will be adjusted to your individual requirements. This will be calculated for you by your doctor.

If you use more Albutein® 50 g/l than you should

If you have been given more Albutein® 50 g/l than required, your blood volume may increase. Tell your doctor immediately.

Signs of overdose may include: headache, trouble breathing, jugular vein congestion (enlarged veins in the neck), high blood pressure, and pulmonary oedema (liquid accumulation in the lungs).

If you forget to use Albutein® 50 g/l

Tell your doctor or pharmacist immediately and follow his/her instructions.

You must not be given a double dose to make up for a forgotten dose.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Albutein® 50 g/l can cause side effects, although not everybody gets them.

- Mild reactions such as flush, skin rash, fever and nausea may occur rarely.
- Severe allergic reactions (anaphylactic shock) may occur very rarely.

For information on viral safety, see section 2.

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: https://yellowcard.mhra.gov.uk or telephone 0808 100 3352. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ALBUTEIN® 50 g/l

Keep out of the reach and sight of children.

Do not use Albutein® 50 g/l after the expiry date which is stated on the bottle label and carton after EXP. The expiry date refers to the last day of that month.

Do not store above 30 ºC. Do not freeze.

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

The solution should be clear or slightly opalescent. Do not use Albutein® 50 g/l if you notice that the solution is cloudy or has deposits.

Once the bottle has been opened, the contents should be used immediately.

Any unused product or waste material should be disposed of in accordance with local requirements. Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Albutein® 50 g/l contains

- The active substance is human albumin. One millilitre of Albutein® 50 g/l contains 50 mg of human plasma protein, of which at least 95% is human albumin.
- The other ingredients are sodium chloride, sodium caprylate, sodium N-acetyltryptophanate and water for injections.

For further information about ingredients see also “Important information about some of the ingredients of Albutein® 50 g/l” at the end of section 2.

What Albutein® 50 g/l looks like and contents of the pack

Albutein® 50 g/l is a solution for infusion. The solution is clear and slightly viscous; it can be almost colourless, slightly yellow, slightly amber or slightly green.

Albutein® 50 g/l is supplied in bottles containing 250 ml and 500 ml of product. Pack size of 1 bottle.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder and Manufacturer Responsible for Batch Release:

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