Package leaflet: information for the user

Albutein 200 g/l, solution for infusion

human albumin

Read all this leaflet carefully before you start using this medicine; 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, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects tell your doctor, pharmacist or nurse. This includes any side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Albutein 200 g/l is and what it is used for

Albutein 200 g/l is a solution for intravenous infusion containing proteins extracted from human plasma (plasma proteins), which is the liquid part of the blood. Each vial/bottle/bag contains a solution of 200 g plasma protein/litre of which at least 95% is human albumin.

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

Albutein 200 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.
Albutein can be used for all age groups. For children, see section 4.

If you have any questions about the use of Albutein 200 g/l please ask your doctor.

2. What you need to know before you use Albutein 200 g/l

Do not use Albutein 200 g/l

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

Warnings and precautions

Talk to your doctor, pharmacist or nurse before you start using Albutein 200 g/l.
Special care should be taken with Albutein 200 g/l

- If you have a special risk due to an increase of blood volume, for example, in case of severe heart diseases, high blood pressure, dilated veins in the esophagus, liquid in the lungs, blood clotting disorders, severe decrease of red blood cells or absence of urine.

- When there are signs of blood volume increase (headache, breathing disorders, jugular vein congestion) or blood pressure increase. The infusion must be stopped immediately.
- When there are signs of allergic reaction. The infusion must be stopped immediately.
- When used on patients with a severe cerebral injury by traumatism.

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 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 Albutein 200 g/l the name and batch number of the medicine are recorded in order to maintain a record of the batches used.

Children

The safety and efficacy of Albutein 200 g/l in children have not been established in controlled clinical trials. However, clinical experience with albumin in children, suggests that no harmful effects are to be expected provided that particular attention is paid to the dose in order to avoid a circulatory overload. See also section 4.

Other medicines and Albutein 200 g/l

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
No specific interactions of human albumin with other medicines are known.

Pregnancy, breast-feeding and fertility

Pregnancy

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.

The safety of Albutein 200 g/l for use in women during pregnancy has not been established in controlled clinical trials. However, clinical experience with albumin suggests that no harmful effects on the course of pregnancy, or on the fetus and the neonate are to be expected.

Breast-feeding

It is unknown whether Albutein 200 g/l is excreted into the breast milk. The excretion of human albumin into the milk has not been studied in animals. The decision whether to continue/discontinue breast-feeding or to continue/discontinue therapy with Albutein should be made taking into account the benefit of breast-feeding for the child and the benefit of Albutein therapy for the mother.

Fertility

No animal reproduction studies have been conducted with Albutein 200 g/l.
However, human albumin is a normal constituent of human blood.

Driving and using of machines

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

Albutein 200 g/l contains sodium

This medicine contains 33.4 mg sodium (main component of cooking/table salt) in each vial of 10 ml, 166.8 mg sodium in each bottle/bag of 50 ml and 333.5 mg sodium in each bottle/bag of 100 ml. This is equivalent to 1.7%, 8.3% and 16.7%, respectively, of the recommended maximum daily dietary intake of sodium for an adult.

This medicine contains potassium, less than 39 mg (1 mmol) per vial/bottle/bag, i.e. essentially 'potassium-free'.

3. How to use Albutein 200 g/l

Albutein 200 g/l is a medicine for hospital use, thus it will be administered in a hospital by the corresponding medical staff.

The dosage and the infusion rate of Albutein 200 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 200 g/l than you should

If you have been given more Albutein 200 g/l than required, tell your doctor immediately.

If you forget to use Albutein 200 g/l

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

4. Possible side effects

Like all medicines, this medicine 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.

Additional side effects in children

There are no specific data to evaluate the possibility of finding different adverse reactions in this population.

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 the national reporting system:

HPRA Pharmacovigilance
Website: www.hpra.ie
By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Albutein 200 g/l

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 container after EXP.

Do not store above 30 ºC.

Do not freeze.

Keep the vial/bottle/bag 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 deposits.

Once the container has been opened to assemble the infusion set, the contents should be used immediately.

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 Albutein 200 g/l contains

- The active substance is human albumin. One milliliter of Albutein 200 g/l contains 200 mg of plasma proteins, of which at least 95% is human albumin.

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

Produced from the plasma of human donors.

For further information about ingredients see also “Albutein 200 g/l contains sodium” at the end of section 2.

What Albutein 200 g/l looks like and contents of the pack

Albutein 200 g/l is a solution for infusion. The solution is clear, slightly viscous, it is almost colourless, yellow, amber or green.

Albutein 200 g/l can be supplied in:

- Vials/bottles, with a chlorobutyl rubber stopper, an aluminum cap, plastic top and plastic shrink band that guarantee the intactness of packaging. Vials contain 10 ml of product and bottles contain 50 ml or 100 ml of product.

- Bags (FlexBag) made of polyethylene, with a protective overwrap made of polypropylene. Bags contain 50 ml or 100 ml of product.

Pack sizes:
- 1 vial with 10 ml per box
- 1 bottle with 50 ml or 100 ml per box

- 1 bag with 50 ml or 100 ml per box

Marketing authorisation holder and manufacturer

Instituto Grifols, S.A.
Can Guasch, 2 - Parets del Vallès
08150 Barcelona – SPAIN

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

Bulgaria, Croatia, Finland, France, Germany, Greece, Iceland, Ireland, Poland, Portugal, Romania, Sweden: **Albutein 200 g/l**
Denmark, Norwegia: **Albumin Grifols 200 g/l**
Italy: **Albumina Umana Grifols 200 g/l**
Spain: **Albutein 200 g/l solución para perfusión**
Slovakia: **Albutein 200 g/l infúzny roztok**
Czech Republic: **Albutein**

This leaflet was last revised in

Detailed information on this medicine is available on the website of HEALTH PRODUCTS REGULATORY AUTHORITY (HPRA)
Website: www.hpra.ie

The following information is intended for healthcare professionals only:

- Albutein 200 g/l can be directly administered by the intravenous route, or it can also be diluted in an isotonic solution (e.g. 5% glucose or 0.9% sodium chloride). The mixture with electrolytic solutions must be performed under aseptic conditions.
- Albumin solutions must not be diluted with water for injections, as this may cause haemolysis in recipients.
- Human albumin must not be mixed with other medicinal products, whole blood or packed red cells.
- 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.
- The infusion is performed by the intravenous route using a sterile, pyrogen-free, single use infusion set. Before inserting the infusion set into the stopper, this must be disinfected using the appropriate antiseptic solution. Once the infusion set and vial/bottle are assembled, the content should be infused immediately.
- The infusion rate should be adjusted according to the individual circumstances and the indication. In plasma exchange the infusion rate should be adjusted to the rate of removal. Hypervolaemia may occur if the dosage and rate of infusion are not adjusted to the patients circulatory situation. At the first clinical signs of cardiovascular overload (headache, dyspnoea, jugular vein congestion), increased blood pressure or raised venous pressure and pulmonary oedema, the infusion is to be stopped immediately.
- If large volumes are administered, the product should be warmed to room or body temperature before use.
- Albumin 200 g/l solution has a corresponding hyperoncotic effect. When concentrated albumin is administered, care must be taken to assure adequate hydration of the patient.
- Patients should be monitored carefully to guard against circulatory overload and hyperhydration.
- When albumin is given, the electrolyte status of the patient should be monitored and appropriate steps taken to restore or maintain the electrolyte balance.
- Care must be taken to ensure adequate substitution of other blood constituents (coagulation factors, electrolytes, platelets and erythrocytes).
- Any unused product should be disposed of in accordance with local requirements.

Bag:

- Do not remove the overwrap until ready for use. Some moisture or condensation may be observed in the protective overwrap. This is normal and does not affect the quality or safety of the albumin solution.
- Check the bag for any leaks prior to use by squeezing it firmly. If leaks are detected, discard the solution.
- To connect the infusion set, break the valve by twisting.
- Once the infusion set and bag are assembled, the content should be infused immediately.
- Do not use bags in series connections. Such use could result in air embolism due to residual air being drawn from the primary bag before the administration of the fluid from the secondary bag is complete.