150 mm

340 mm

GRIFOLS

PACKAGE LEAFLET: INFORMATION FOR THE USER

Human Albumin Grifols® 200 g/l
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, 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, talk to your doctor, pharmacist 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 GRIFOLS® 200 g/l IS AND WHAT IT IS USED FOR

Human Albumin Grifols® 200 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 200 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.
Human Albumin Grifols® 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.
If you have any questions about the use of Human Albumin Grifols® 200 g/l please ask your doctor.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE HUMAN ALBUMIN GRIFOLS® 200 g/l

Do not use Human Albumin Grifols® 200 g/l
If you are allergic (hypersensitive) to human albumin protein or any of the other ingredients of this medicine (listed in section 6) (see "Important information about some of the ingredients of Human Albumin Grifols® 200 g/l" at the end of this section).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before using Human Albumin Grifols® 200 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 (inflamed veins in the esophagus)
  - 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 Human Albumin Grifols® 200 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,
- 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 specifications by established processes.
It is strongly recommended that every time you receive a dose of Human Albumin Grifols® 200 g/l the name and batch number of the medicine are recorded in order to maintain a record of the batches used.

Other medicines and Human Albumin Grifols® 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
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.

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

Important information about some of the ingredients of Human Albumin Grifols® 200 g/l
Patients on a controlled sodium diet should take into consideration that this medicine contains 36.8 mg (1.6 mmol) sodium per vial of 10 ml, 184 mg (8 mmol) sodium per vial of 50 ml, and 368 mg (16 mmol) sodium per vial of 100 ml.
This medicine contains very low levels of potassium and can be considered to be "potassium free".

3. HOW TO USE HUMAN ALBUMIN GRIFOLS® 200 g/l

Human Albumin Grifols® 200 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 Human Albumin Grifols® 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.

Use in children
The safety and efficacy of Human Albumin Grifols® 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.

If you use more Human Albumin Grifols® 200 g/l than you should
If you have been given more Human Albumin Grifols® 200 g/l than required, consult your doctor or pharmacist immediately.

If you forget to use Human Albumin Grifols® 200 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, 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.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517. Website: www.hpra.ie, E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE HUMAN ALBUMIN GRIFOLS® 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 bottle label and carton after EXP.
Do not store above 25 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 this medicine if you notice that the solution is cloudy or has deposits.
Once the bottle has been opened, 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 Human Albumin Grifols® 200 g/l contains
- The active substance is human albumin. One millilitre of Human Albumin Grifols® 200 g/l contains 200 mg of human plasma protein, of which at least 95% is human albumin.
- The other ingredients are sodium chloride, sodium caprylate, N-acetyltryptophan, sodium hydroxide or hydrochloric acid (for pH adjustment) and water for injections.

For further information about ingredients see also "Important information about some of the ingredients of Human Albumin Grifols® 200 g/l" at the end of section 2.

What Human Albumin Grifols® 200 g/l looks like and contents of the pack
Human Albumin Grifols® 200 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.
Human Albumin Grifols® 200 g/l is supplied in vials containing 10 ml, 50 ml and 100 ml of product. Pack size of 1 vial.

Marketing Authorisation Holder and Manufacturer
Instituto Grifols, S.A.
Can Guasc, 2 - Parets del Vallès
08150 Barcelona - SPAIN

This leaflet was last revised in MM/YYYY.

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 medical or healthcare professionals only:
- Human Albumin Grifols® 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 and packed red cells.
- 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.
- 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 container has been penetrated, 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), or increased blood pressure, 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.
- 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 or waste material should be disposed of in accordance with local requirements.