PACKAGE LEAFLET: INFORMATION FOR THE USER

Human Albumin Grifols® 50 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 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 Grifols® 50 g/l is and what it is used for

Human Albumin Grifols® 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.

Human Albumin Grifols® 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.

You must talk to a doctor if you do not feel better or if you feel worse.

2. What you need to know before you use Human Albumin Grifols® 50 g/l

Do not use Human Albumin Grifols® 50 g/l

If you are allergic 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® 50 g/l at the end of this section).

Warnings and precautions

• 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® 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,

• 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 Grifols® 50 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® 50 g/l

Tell your doctor 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 and breast-feeding

If you are pregnant or breast-feeding you must tell your doctor who will decide if Human Albumin Grifols® 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 Human Albumin Grifols® 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 bottle of 250 ml.

This medicine contains very low levels of potassium and can be considered to be "potassium free".

3. How to use Human Albumin Grifols® 50 g/l

Human Albumin Grifols® 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 Human Albumin Grifols® 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.

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 suspected adverse reactions
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® 50 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.
Any unused product or waste material should be disposed of in accordance with local requirements.

6. Contents of the pack and other information

What Human Albumin Grifols® 50 g/l contains

- The active substance is human albumin. One millilitre of Human Albumin Grifols® 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, N-acetyltryptophan, hydrochloric acid or sodium hydroxide (to adjust pH) and water for injections.

For further information about ingredients see also "Important information about some of the ingredients of Human Albumin Grifols® 50 g/l" at the end of section 2.

What Human Albumin Grifols® 50 g/l looks like and contents of the pack

Human Albumin Grifols® 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.

Human Albumin Grifols® 50 g/l is supplied in a bottle containing 250 ml of product. Pack size of 1 bottle.

Marketing Authorisation Holder and Manufacturer

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

This leaflet was last revised in 08/2014.

Detailed information on this medicine is available on the PRODUCT REGULATORY AUTHORITY (HPRA). Website: www.hpra.ie