PACKAGE LEAFLET: INFORMATION FOR THE USER

Albumin Octapharma 200 g/l

Human albumin 200 g/l, Solution for infusion

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 pharmacist.
- 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.

In this leaflet:

1. WHAT ALBUMIN OCTAPHARMA IS AND WHAT IT IS USED FOR

Albumin Octapharma belongs to the pharmacotherapeutic group: plasma substitutes and plasma protein fractions.

The product is given to patients to restore and maintain circulating blood volume where a deficiency in volume has been demonstrated.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE ALBUMIN OCTAPHARMA

Do not use Albumin Octapharma :

- if you are allergic (hypersensitive) to albumin preparations or any of the other ingredients

Warnings and precautions

- Talk to your doctor, pharmacist or nurse before using Albumin Octapharma.

Take special care with Albumin Octapharma :

- If you develop an allergic reaction to this albumin treatment, the infusion will be stopped and your doctor will recommend an alternative treatment.
- if you are at special risk from increased blood volume eg in case of some heart conditions, high blood pressure, fluid in the lung, bleeding disorders, low red blood cell count, dilated veins of the oesophagus or no urine output.
- when there are signs for increased blood volume (headache, breathing disorder, jugular vein congestion), increased blood pressure. The infusion should be stopped immediately

Virus safety

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
- testing of each donation and pools of plasma for signs of virus/infections
- steps included by the manufacturers 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 specifications by established processes.

It is strongly recommended that every time you receive a dose of Albumin Octapharma the name and batch number of the product are recorded in order to maintain a record of the batches used.

Other medicines and Albumin Octapharma

No interactions of human albumin with other products are known so far. However, Albumin Octapharma solution should not be mixed in the same injection with other drugs, whole blood or packed red cells.

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

Pregnancy and breast-feeding

Human albumin is a normal constituent of human blood. No harmful effects are known when this product is used during pregnancy or breast-feeding. Particular care should be taken to adjust blood volume in pregnant women.

Driving and using machines

There are no indications that human albumin impairs the ability to drive or to operate machines.

Albumin Octapharma contains sodium

This medicine contains 328 - 362 mg sodium (main component of cooking/table salt) per 100 ml albumin solution. This is equivalent to up to 18.1% of the recommended maximum daily dietary intake of sodium for an adult.

This medicine contains less than 1 mmol (39 mg) potassium per 100 ml solution, i.e. essentially "potassium-free".

3. HOW TO USE ALBUMIN OCTAPHARMA

Albumin Octapharma is ready for use as an infusion ("drip") into a vein. The dosage and infusion rate (how quickly you are given albumin into a vein) will depend on your particular condition. Your doctor will decide what treatment is best for you.

The product can be given to premature infants and dialysis patients.

If you use more Albumin Octapharma than you should:
If the dosage and rate of infusion are too high, you may develop headache, high blood pressure and discomfort breathing. The infusion should be stopped immediately and your doctor will decide if any other treatment is necessary.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Albumin Octapharma can cause side effects, although not everybody gets them.

Side effects after infusion of human albumin are rare and they normally disappear when the infusion-rate is slowed down or stopped.

Rare side effects (frequency: more than 1 of 10,000 and fewer than 1 of 1,000 transfusions):

Low blood pressure or allergic reaction.

Very rare side effects (frequency: fewer than 1 of 10,000 transfusions):

Severe allergic reaction; confusional state; headache; increased or decreased heart rate; high blood pressure; heat sensation; shortage of breath; feeling sick; nettle rash; swelling around eyes, nose, mouth; rash; increased sweating; fever; chills.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V*. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ALBUMIN OCTAPHARMA 200 g/l

Keep out of the reach and sight of children.
Do not use Albumin Octapharma after the expiry date which is stated on the label.

Store and transport below +25°C. Keep the container in the outer carton in order to protect from light. Do not freeze.

Before use the product should be warmed to room or body temperature.

The solution should be clear or slightly opalescent. Do not use solutions which are cloudy or have deposits. Once the infusion container has been opened, the content should be used immediately. 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. CONTENT OF THE PACK AND OTHER INFORMATION

What Albumin Octapharma contains
The active substance is human albumin.

One bottle of 50 ml contains 10 g of human albumin.
One bottle of 100 ml contains 20 g of human albumin.

The other ingredients are sodium, potassium, N-Acetyl-DL-tryptophan, caprylic acid and water for injections.

What Albumin Octapharma looks like and contents of the pack

Albumin Octapharma is a solution for infusion into a vein and is available in a bottle (10 g/50 ml, 20 g/100 ml). Pack size of 1.

Marketing Authorisation Holder and Manufacturer
Marketing authorisation holder:
[to be completed nationally]

Manufacturer: Octapharma Pharmazeutika, Produktionsges.m.b.H., Oberlaaerstrasse 235, A-1100 Vienna, Austria
and

Octapharma S.A.S., 70-72 rue du Maréchal Foch, BP33, 67380 Lingolsheim, France

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