PACKAGE LEAFLET: INFORMATION FOR THE USER

Obruman 200 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 OBRUMAN SOLUTION FOR INFUSION IS AND WHAT IT IS USED FOR

Obruman solution for infusion contains the human protein albumin and is administered into a vein. Human albumin is a normal constituent of human plasma and acts like albumin present in your body when given as a replacement therapy. Albumin stabilises circulating blood volume and is a carrier of hormones, enzymes, medicinal products and toxins.

Albumin is used for restoration and maintenance of circulating blood volume in your body where volume deficiency has been demonstrated and your doctor considers replacement therapy appropriate.

The product is provided in one strength: Obruman 200 g/l .

2. BEFORE YOU USE OBRUMAN SOLUTION FOR INFUSION

Do not use Obruman solution for infusion
- if you are allergic (hypersensitive) to albumin preparations or any of the other ingredients of Obruman solution for infusion.

Take special care with Obruman solution for infusion,
if you are suffering from any of the following diseases:
- decompensated cardiac insufficiency
- hypertension
- oesophageal varices
- pulmonary oedema
- tendency to bleedings
- severe anaemia

- anuria due to e.g. renal impairment

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 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, such as with Obruman solution for infusion.

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

Using 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. However, other medicines are not known to affect your treatment with Obruman solution for infusion.

Pregnancy and breast-feeding
Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
Albumin has no harmful effects on ability to drive and use machines.

Important information about some of the ingredients of Obruman solution for infusion
This medicine contains sodium, the concentration of which is:
– in Obruman 200 g/l solution for infusion 100 mmol per litre.
This should be taken into consideration by patients on a controlled sodium diet.

3. HOW TO USE OBRUMAN SOLUTION FOR INFUSION

Obruman solution for infusion will be given as a slow infusion. A doctor or a nurse will administer the solution into your vein through an infusion set. The dose and infusion rate will be adjusted to your individual requirements by your doctor. The dose required depends on your length and weight, the severity of your condition and on your continuing fluid and protein losses.

Obruman 200 g/l can be administered directly or it can also be diluted in an isotonic solution (e.g. 5% glucose or 0.9% sodium chloride). However, it must not be diluted with water for injections as this may cause haemolysis in recipients.

Albumin must not be mixed with other medicinal products, whole blood and packed red cells.

During the infusion your blood pressure, heart function, blood count and breathing will be checked regularly in order to ascertain that your dosage is appropriate.

If you are given more Obruman solution for infusion than you should
Hypervolaemia may occur if you are given overdose. The signs are e.g. headache, dyspnoea and increased blood pressure. Should these signs occur, the infusion will be stopped immediately. You may be given treatment to remove the excess fluid.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Obruman solution for infusion can cause side effects, although not everybody gets them.

Rare side effects, which occur in 1-10 out of 10 000 treated patients:
flush, urticaria, fever and nausea.
These reactions normally disappear rapidly when the infusion rate is slowed down or the infusion is stopped.

Very rare side effects, which occur in less than 1 out of 10 000 treated patients:
anaphylactoid reactions such as shock.
In these cases, the infusion will be stopped and an appropriate treatment will be initiated.

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.

5. HOW TO STORE OBRUMAN SOLUTION FOR INFUSION

Keep out of the reach and sight of children.

Do not use the product after the expiry date which is stated on the package.

Obruman 200 g/l
10 ml pack size: Store in a refrigerator (2°C – 8°C). 50 ml and 100 ml pack size: Store below 25°C.
Do not freeze. Store in the original package in order to protect from light.

Do not use Obruman solution for infusion if you notice that the solution is cloudy or has deposits. This may indicate that albumin is unstable or that the solution has become contaminated.

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 Obruman solution for infusion contains

Obruman 200 g/l
- The active substance is human albumin 200 g/l; in vial of 2 g/10 ml or 10 g/50 ml or 20 g/100 ml

- The other ingredients are sodium caprylate, sodium hydroxide or hydrochloric acid, sodium chloride and water for injections.

What Obruman solution for infusion looks like and contents of the pack

Obruman 200 g/l solution for infusion
Obruman 200 g/l is presented as a solution for infusion in a vial (10 ml or 50 ml or 100 ml – pack size of 1).

The solution is clear, slightly viscous; it is almost colourless, yellow, amber or green.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Oxbridge Pharma Ltd
15 Fitzroy House, Lynwood Drive
Worcester Park, Surrey, KT4 7AT
United Kingdom

This leaflet was last amended in xx.xx.xxxx