Package leaflet: Information for the user

Flexbumin 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 signs of illness 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 Flexbumin 200 g/l is and what it is used for
2. What you need to know before you use Flexbumin 200 g/l
3. How to use Flexbumin 200 g/l
4. Possible side effects
5. How to store Flexbumin 200 g/l
6. Contents of the pack and other information

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

Flexbumin 200 g/l is a solution of plasma protein and belongs to the pharmacotherapeutic group of plasma substitutes and plasma protein fractions. Plasma is the fluid in which blood cells are suspended.
This medicine is used for restoration and maintenance of circulating blood volume when there is not enough blood volume.

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

Do not use Flexbumin 200 g/l
- if you are allergic to human albumin or any of the other ingredients of this medicine (listed in section 6).

Warnings and Precautions

Talk to your doctor, pharmacist or nurse before using Flexbumin 200 g/l.
- If you get headache, difficulties in breathing or feeling faint during the treatment please tell your doctor or nurse. It can be an allergic reaction.
- If you have:
  – decompensated heart failure
  – high blood pressure
  – oesophageal varices (swelled veins in the oesophagus)
  – pulmonary oedema (fluid in the lungs)
  – a tendency to spontaneous bleeding
  – severe anemia (lack of red blood cells)
  – decreased urine formation

inform your doctor so that he/she can take appropriate precautions.

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.

It is strongly recommended that every time you receive a dose of Flexbumin 200 g/l the name and batch number of the product are recorded in order to maintain a record of the batches used.

Other medicines and Flexbumin 200 g/l
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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. Your doctor will decide if you can use Flexbumin 200 g/l during pregnancy or breast-feeding.

The effect of Flexbumin 200 g/l on fertility has not been studied.

Children and adolescents
The safety and efficacy of the use of Albumin (Human) solution in children and adolescents have not been established in company-sponsored clinical trials. Since limited data on the use of Flexbumin 200 g/l in children are available in literature, the product should only be used if the benefits clearly outweigh the potential risks.

Driving and using machines
No effect on the ability to drive or use machines has been observed.

Flexbumin 200 g/l contains sodium

50 mL bag:
This medicine contains 149.5-184 mg sodium (main component of cooking/table salt) in each bag. This is equivalent to 7.5-9.2 % of the recommended maximum daily dietary intake of sodium for an adult.

100 mL bag:
This medicine contains 299-368 mg sodium (main component of cooking/table salt) in each bag. This is equivalent to 15-18.4 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use Flexbumin 200 g/l

Flexbumin 200 g/l is a medicine for hospital use. It will therefore be administered to you in a hospital by appropriate health care personnel. Your doctor will determine the amount of product to be administered, the frequency of dosing and the duration of treatment based on your specific condition.

If you use more Flexbumin 200 g/l than you should
Flexbumin 200 g/l is administered under medical supervision only. An overdosage is therefore highly unlikely to occur. But in case the dosage and infusion rate are too high, an abnormal increase in blood volume (hypervolaemia) may occur. This may lead to an overload of the heart and circulatory system (cardiovascular overload) First signs of such an overdose include:

- headache

- breathing difficulty (dyspnoea)
- swelling of your neck veins (jugular vein congestion)

Tell your doctor, pharmacist or nurse immediately if you notice such symptoms.

Your doctor, pharmacist or nurse may also detect signs like:
- an increased blood pressure (hypertension)
- a raised central venous pressure
- fluid in the lungs (pulmonary oedema)

In all these cases, the infusion must be stopped immediately by your doctor, pharmacist or nurse and your haemodynamic parameters have to be carefully monitored.

Use in children and adolescent patients
Your doctor will decide whether children and adolescents can receive Flexbumin 200 g/l or not.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

	Very common	**Common**	**Uncommon**	**Rare**	**Very rare**
Immune system disorders					anaphylactic shock
Gastrointestinal disorders				nausea (feeling sick)	
Skin and subcutaneous tissue disorders				flushing, skin rash	
General disorders and administration site conditions				fever	

Very common	in more than 1 in 10 patients treated
Common	in less than 1 in 10, but more than 1 in 100 patients treated
Uncommon	in less than 1 in 100, but more than 1 in 1000 patients treated
Rare	in less than 1 in 1000, but more than 1 in 10 000 patients treated
Very rare	in less than 1 in 10 000 patients treated, including isolated cases

● The rare side effects disappear quickly when the infusion-rate is decreased or stopped.
● If anaphylactic shock (severe allergic reactions) occurs, the infusion should be stopped immediately and appropriate treatment 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.

Other side effects observed after placing Human Albumin on the market are: Hypersensitivity/Allergic reactions, Headache, Rapid heart beat, Abnormally low blood pressure, Breathlessness or breathing discomfort, Vomiting, Altered sense of taste, Hives, Itchiness, Chills, Heart attack, Irregular heart beat, Accumulation of fluid in the lung.

Additional side effects in children and adolescents

Safety data in children and adolescent patients are limited. No additional side effects in children and adolescents are known.

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 the national reporting system listed below.

United Kingdom
Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Ireland
HPRA PharmacovigilanceWebsite: www.hpra.ie

Malta
ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Flexbumin 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 bag and the carton. The expiry date refers to the last day of that month.

Do not store above 25°C.
Do not freeze.
Keep the bag in the outer carton in order to protect from light.

Once the package has been opened, the contents must be used immediately.
Do not use Flexbumin 200 g/l if you notice that the solution is cloudy or has deposits.

6. Contents of the pack and other information

What Flexbumin 200 g/l contains

- The active substance is human albumin.
  1 liter of solution contains 200 g of total protein, of which at least 95% is human albumin.
- The other ingredients are sodium chloride, sodium caprylate, sodium acetyltryptophanate and water for injections.

Total amount of sodium ions: 130 –160 mmol/l

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

Flexbumin 200 g/l is presented as a solution for infusion in a bag. Pack sizes are 12 x 100 ml (2 boxes of 6 or 12 single units), 24 x 50 ml (2 boxes of 12 or 24 single units), 1 x 100 ml (single unit) and 1 x 50 ml (single unit).

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

Marketing Authorisation Holder and Manufacturer

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The following information is intended for medical or healthcare professionals only:

Before and during administration of Flexbumin 200 g/l

- Albumin solutions must not be diluted with water for injections as this may cause haemolysis in recipients.
- If large volumes are administered, the product should be warmed to room or body temperature before use.
- For safety reasons the name and batch number of Flexbumin 200 g/l should be recorded when administered to a patient.
- Hypervolaemia may occur if the dosage and rate of infusion are not adjusted to the patient's 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.

Preparation
Flexbumin 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).

Administration of Flexbumin 200 g/l

- Do not use the bag if the tip protector is damaged, detached or missing.
- Use only if the bag seals are intact. Discard in case of leak.
- 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.
- Infusion is performed by the intravenous route using a disposable sterile and pyrogen-free infusion set. Before inserting the infusion set in the cap, this should be disinfected with an appropriate antiseptic. Once the infusion set is attached to the bag, the contents should be perfused 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.

Shelf life
Once the container has been opened, the contents should be used immediately. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Incompatibilities
This medicinal product must not be mixed with other medicinal products, whole blood and packed red cells (except an isotonic solution e.g. 5% glucose or 0.9% sodium chloride). Further human albumin should not be

mixed with protein hydrolysates (e.g. parenteral nutrition) or solutions containing alcohol since these combinations may cause the proteins to precipitate.