Package leaflet: Information for the user

HUMAN ALBUMIN BAXALTA 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, 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 Human Albumin Baxalta 50 g/l is and what it is used for

Human Albumin Baxalta 50 g/l contains a protein called albumin found in the liquid component of the blood (the plasma) and belongs to the group of medical products called "plasma substitutes and plasma protein fractions". It is made from human blood collected from blood donors.

A vial of 250 ml contains 12.5 g of human albumin.
A vial of 500 ml contains 25 g of human albumin.

Human albumin is used to restore and maintain blood volume in patients who have lost blood or fluid due to certain medical conditions. The choice of albumin rather than an artificial substitute and the dose needed will depend on the clinical situation of the individual patient.

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

Do not use Human Albumin Baxalta 50 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 Human Albumin Baxalta 50 g/l.
- if you think you have an allergic reaction during the treatment, with difficulty breathing, feeling faint or other symptoms. If this happens, tell your doctor or nurse immediately because the infusion will have to be stopped and medical treatment for shock may need to be implemented.
- if you have:
  – uncontrolled heart failure
  – high blood pressure
  – oesophageal varices (swollen veins in the oesophagus)
  – pulmonary oedema (fluid on the lungs)
  – a tendency to spontaneous bleeding

– severe anemia (lack of red blood cells)
– no urine formation.
If you think any of these applies to you, inform your doctor so that he/she can take appropriate precautions.

When medicines are made from human blood or plasma, certain steps 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 Human Albumin Baxalta 50 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 Human Albumin Baxalta 50 g/l
- Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
- No specific complications of taking human albumin with other medicinal products are known.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby ask your doctor. Your doctor will decide if you can use Human Albumin Baxalta 50 g/l during pregnancy or breast-feeding.

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

Human Albumin Baxalta 50 g/l contains sodium

250 mL vial:
This medicinal product contains 747.5 - 920 mg sodium (main component of cooking/table salt) per vial. This is equivalent to 37.38 - 46 % of the recommended maximum daily intake of 2 g sodium for an adult.

500 mL vial:
This medicinal product contains 1495 - 1840 mg sodium (main component of cooking/table salt) per vial. This is equivalent to 74.75 - 92 % of the recommended maximum daily intake of 2 g sodium for an adult.

3. How to use Human Albumin Baxalta 50 g/l

Human Albumin Baxalta 50 g/l is a medicine for hospital use. It will therefore be administered in a hospital by appropriate health care personnel. Your doctor will establish the amount of product to be administered, the frequency of dosing and the duration of treatment based on your specific condition. He/she will monitor your condition, measuring your blood pressure and heart rate and taking blood tests, while you are receiving Human Albumin to make sure that you are not given too much. If you experience headache, difficulties in breathing or increased blood pressure, please tell your doctor.

If you take more Human Albumin Baxalta 50 g/l than you should
If you may have got more Human Albumin Baxalta 50 g/l than you should consult your doctor or pharmacist immediately.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.
If any of the side effects listed below occurs, the infusion should be stopped immediately and appropriate treatment initiated:

- anaphylactic shock (very rare: may affect up to 1 in 10 000 people)
- hypersensitivity/allergic reactions (not known: frequency cannot be estimated from the available data)

The following side effects have also been reported:

Rare: may affect up to 1 in 1,000 people
- nausea (feeling sick)
- flushing
- skin rash
- fever

Not known: frequency cannot be estimated from the available data
- headache
- altered sense of taste
- heart attack
- irregular heartbeat
- rapid heartbeat
- abnormally low blood pressure
- accumulation of fluid in the lung
- breathlessness or breathing discomfort
- vomiting
- hives
- itchiness
- chills

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

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 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 Pharmacovigilance, Website: 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 Human Albumin Baxalta 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 label. The expiry date refers to the last day of that month.
Do not store above 25°C.
Do not freeze.
Keep the glass vial 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 Human Albumin Baxalta 50 g/l if you notice the solution is cloudy or has particles in it.

6. Contents of the pack and other information

What Human Albumin Baxalta 50 g/l contains

- The active substance is: human albumin.
  Every 100 ml contain 5 g of total protein, of which at least 95% is human albumin.
- The other ingredients are: sodium chloride, sodium caprylate, sodium N-acetyltryptophanate, water for injection.

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

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

It is a clear, slightly thick liquid; it is almost colourless, yellow, amber or green. It is a sterile solution for intravenous infusion in 250 ml or 500 ml glass vials.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Baxalta Innovations GmbH
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Manufacturer
Baxter AG
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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

Baxalta UK Limited
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This medicinal product is authorised in the Member States of the European Economic Area

and in the United Kingdom (Northern Ireland) under the following names:

Country	**Invented Name**
Austria	Human Albumin Takeda 50 g/l
Bulgaria, Cyprus, Germany, Greece	Human Albumin 50 g/l Baxalta
Denmark, Estonia, Finland, Iceland, Latvia, Lithuania, Norway, Sweden	Albumin Baxalta 50 g/l
Belgium, Ireland, Luxembourg, Malta, United Kingdom (Northern Ireland)	Human Albumin Baxalta 50 g/l
Italy	Albumina Baxalta 50 g/l
Poland	Human Albumin 50 g/l Takeda
Romania	Albumină Umană Baxalta 50 g/l soluţie perfuzabilă
Slovenia	HUMANI ALBUMIN 50 g/l BAXALTA

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The following information is intended for healthcare professionals only:

- Human Albumin Solution 50 g/l should be administered by the intravenous route, infusing the package contents directly.
- Human Albumin Solution 50 g/l should not be diluted with water for injection, since this could cause hemolysis in the recipient of the product.
- Do not use unless seal is intact. If leaks are found, discard.
- Solutions should be clear, slightly viscous, almost colourless, yellow, amber or green.. Solutions that are turbid or showing sediments should not be used, since this could be an indication that the protein is unstable or the solution has been contaminated. Once the package has been opened, its contents must be used immediately.
- 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 vial, the contents should be perfused immediately. Unused solutions should be adequately discarded.
- 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 ofremoval.
- If large volumes are administered, the product should be warmed to room temperature before use.
- When concentrated albumin is administered, adequate hydration of the patient must be ensured. Patients should be adequately monitored to prevent circulatory overload and overhydration.
- When albumin is administered, the electrolyte balance of the patient should be monitored and, if required, appropriate measures should be taken to restore or maintain it.
- Adequate replacement of other blood components (coagulation factors, electrolytes, platelets and erythrocytes) must be ensured.
- For safety reasons, the batch number of Human Albumin Baxalta 50 g/l administered should be recorded.
- Human albumin must not be mixed with other medicinal products, whole blood and packed red cells. 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.
- Hypervolaemia may occur if the dosage and rate of infusion are too high. At the first clinical signs of cardiovascular overload (headache, dyspnoea, jugular vein congestion), or increased

blood pressure, raised central venous pressure, and pulmonary oedema, the infusion should be stopped immediately and the patient's haemodynamic parameters carefully monitored.