CSL Behring

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have 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.

Human Albumin 20 % Behring, low salt

Solution for infusion

Active ingredient: Human albumin

QUALITATIVE AND QUANTITATIVE COMPOSITION

Human Albumin 20 % Behring, low salt, is a solution containing 200 g/l of total protein of which at least 96 % is human albumin.
100 ml contain at least 19.2 g of human albumin.
50 ml contain at least 9.6 g of human albumin.
The solution is hyperoncotic.

Other ingredients

	mmol/l
Sodium ions	125
Caprylate	16
N-acetyl-D,L-tryptophan	16
Chloride ions	max. 100

HCl or NaOH (in small amounts for pH adjustment),
Water for injections

PHARMACEUTICAL FORM AND PRESENTATIONS

Pharmaceutical form

Solution for infusion.
A clear, slightly viscous liquid; it is almost colourless, yellow, amber or green.

Presentations

Infusion bottle with 50 ml
Infusion bottle with 100 ml
Not all pack sizes may be marketed.

PHARMACOTHERAPEUTIC GROUP

Plasma substitutes and plasma protein fractions, albumin
ATC code: B05A A01

NAME AND ADDRESS OF THE MANUFACTURER AND MARKETING AUTHORISATION HOLDER

CSL Behring GmbH
Emil-von-Behring-Str. 76
35041 Marburg
Germany

THERAPEUTIC INDICATIONS

Increase in oncotic pressure in case of oncotic deficiency.
Diluted as a 4 – 5 % solution for iso-oncotic volume replacement with long-term effect. Therapy of albumin deficiency.

CONTRAINDICATIONS

Hypersensitivity to albumin preparations or to any of the excipients of the product.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Suspicion of allergic or anaphylactic type reactions (reaction like an allergic shock) requires immediate discontinuation of the injection. In case of shock, standard medical treatment for shock should be implemented.

Albumin should be used with caution in conditions where hypervolaemia (oversized blood volume) and its consequences or haemodilution (dilution of the blood) could represent a special risk for the patient. Examples of such conditions are:
- decompensated cardiac insufficiency (severe heart muscle deficiency)
- hypertension (increased blood pressure)
- oesophageal varices (disease of the gullet vessels)
- pulmonary oedema
- haemorrhagic diathesis (increased tendency to bleeding)
- severe anaemia (severe red blood cell deficiency)
- renal and post-renal anuria (kidney failure)

The colloid-osmotic effect of human albumin 200 or 250 g/l is approximately four times that of blood plasma. Therefore, when highly concentrated albumin is administered, care must be taken to assure adequate hydration (fluid supply) of the patient. Patients should be monitored carefully to guard against circulatory overload or hyperhydration (increased volume of total body water).
200 – 250 g/l human albumin solutions are relatively low in electrolytes compared to the 40 – 50 g/l human albumin solutions. When albumin is given, the electrolyte status of the patient should be monitored (see section "Posology and method of administration") and appropriate steps taken to restore or maintain the electrolyte balance.
Albumin solutions must not be diluted with water for injections as this may cause haemolysis (destruction of red cells) in recipients.
If comparatively large volumes are to be replaced, controls of coagulation and haematocrit are necessary. Care must be taken to ensure adequate substitution of other blood constituents (coagulation factors, electrolytes, platelets and erythrocytes).

Hypervolaemia may occur if the dosage and rate of infusion are not adjusted to the patients circulatory situation. At the first clinical signs of cardiovascular overload (headache, dyspnoea [difficulty in breathing], jugular vein congestion), or increased blood pressure, raised venous pressure or pulmonary oedema, the infusion is to be stopped immediately.
Human Albumin 20 % Behring, low salt contains 125 mmol sodium per litre. To be taken into consideration by patients on a controlled sodium diet.

Pregnancy and lactation
The safety of Human Albumin 20 % Behring, low salt, for use in human pregnancy has not been established in controlled clinical trials. However, clinical experience with albumin suggests that no harmful effects on the course of pregnancy, or on the foetus and the neonate are to be expected, particularly since human albumin is a normal constituent of human blood. No animal reproduction studies have been conducted with Human Albumin 20 % Behring, low salt. Experimental animal studies are insufficient to assess the safety with respect to reproduction, development of the embryo or foetus, the course of gestation and peri- and postnatal development.

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, 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 20 % Behring, low salt, the name and batch number of the product are recorded in order to maintain a record of the batches used.

INTERACTIONS WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTIONS

No specific interactions of human albumin with other medicinal products are known.

Incompatibilities
Human Albumin 20 % Behring, low salt, must not be mixed with other medicinal products (except the recommended diluents in section "Posology and method of administration"), whole blood and packed red cells.

POSOLOGY AND METHOD OF ADMINISTRATION

The concentration of the albumin preparation, dosage and the infusion-rate should be adjusted to the patient's individual requirements.

Posology
The dose required depends on the size of the patient, the severity of trauma or illness and on continuing fluid and protein losses. Measures of adequacy of circulating volume and not plasma albumin levels should be used to determine the dose required.
If human albumin is to be administered, haemodynamic performance should be monitored regularly; this may include:
– arterial blood pressure and pulse rate
– central venous pressure
– pulmonary artery wedge pressure
– urine output
– electrolyte
– haematocrit/haemoglobin

Overdose
Hypervolaemia may occur if the dosage and rate of infusion are too high. At the first clinical signs of cardiovascular overload (headache, difficulty in breathing, jugular vein congestion), or increased blood pressure, raised central venous pressure or pulmonary oedema, the infusion should be stopped immediately and the patient's haemodynamic parameters carefully monitored.

Method of administration
Human albumin can be administered by the intravenous route, either undiluted or after dilution in an isotonic solution (e.g. 5 % glucose or 0.9 % sodium chloride).
Albumin solutions must not be diluted with water for injections as this may cause haemolysis in recipients.
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.
If large volumes are administered, the product should be warmed to room or body temperature before use.
Do not use solutions which are cloudy or contain residues (deposits/particles). This may indicate that the protein is unstable or that the solution has become contaminated.

UNDESIRABLE EFFECTS

If you experience reactions, especially those which are not mentioned in this package insert, please inform your doctor or pharmacist.
The following adverse reactions are based on post marketing experience and were observed very rarely (<1/10,000 including reported single cases):
- General disorders and administration site conditions:
  Chills, fever, nausea, vomiting, headache, malaise and flush.
- Immune system disorders:
  Hypersensitivity reactions or allergic-anaphylactic reactions such as rash, itching, urticaria, dyspnoea, tachycardia, bradycardia, hypotension. These reactions might in single cases be reaching as far as life-threatening shock.

Mild reactions normally disappear rapidly after the infusion rate has been slowed down or the infusion stopped. In case of severe reactions (e.g. anaphylactic shock) the infusion has to be stopped immediately and appropriate treatment instituted. For safety with respect to transmissible agents, see section "Special warnings and precautions for use".

STORAGE AND STABILITY

Do not store above +25 °C. Do not freeze.
Keep the infusion bottle in the outer carton in order to protect from light.
Human Albumin 20 % Behring, low salt, must not be used after the expiry date given on the pack and container.
Keep out of the reach and sight of children.
Once the container has been opened, the contents have to be used immediately.
Any unused product or waste material should be disposed of in accordance with local requirements.

DATE OF LAST REVISION

March 2008