UMAN ALBUMIN 200 g/l Solution for infusion
UMAN ALBUMIN 250 g/l Solution for infusion
B05AA01 Human albumin from human plasma

QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance

	UMAN ALBUMIN 200 g/l	UMAN ALBUMIN 250 g/l
Solution containing total plasma proteins to	20%	25%
of which human albumin at least to	95%	95%
a vial of 50 ml contains human albumin equal to	10 g	12,5 g
a vial of 100 ml contains human albumin equal to	20 g	---
The solution is	hyperoncotic	hyperoncotic

List of excipients

1 litre of solution for infusion contains:

UMAN ALBUMIN 200 g/l

Sodium chloride	4.52 g/l
Sodium caprylate	2.660 g/l (16 mmoles/l)
Acetyltryptophan	3.940 g/l (16 mmoles/l)
Water for injections	up to 1000 ml
Total concentration of sodium	123.5 – 136.5 mmoles/l

UMAN ALBUMIN 250 g/l

Sodium chloride	3.52 g/l
Sodium caprylate	3.325 g/l (20 mmoles/l)
Acetyltryptophan	4.925 g/l (20 mmoles/l)
Water for injections	up to 1000 ml
Total concentration of sodium	123.5 – 136.5 mmoles/l

PHARMACEUTICAL FORM AND CONTENTS

Solution for infusion.
A clear, slightly viscous liquid; it is almost colourless, yellow, amber or green.
UMAN ALBUMIN 200 g/l: 50 ml and 100 ml vial
UMAN ALBUMIN 250 g/l: 50 ml vial

PHARMACOTHERAPEUTICAL CATEGORY

Plasma substitutes and plasma protein fractions: Human Albumin.

MARKETING AUTHORISATION HOLDER

Kedrion S.p.A. - Loc. Ai Conti, 55020 Castelvecchio Pascoli, Barga (Lucca) Italy.

PRODUCED AND CONTROLLED BY:

Kedrion S.p.A. - 55027 Bolognana, Gallicano (Lucca) Italy.

THERAPEUTIC INDICATIONS

Restoration and maintenance of circulating blood volume where volume deficiency has been demonstrated, and use of a colloid is appropriate.
The choice of albumin rather than artificial colloid will depend on the clinical situation of the individual patient, based on official recommendations.

CONTRAINDICATIONS

Hypersensitivity to albumin preparations or to any of the excipients.

SPECIAL PRECAUTIONS FOR USE

Suspicion of allergic or anaphylactic type reactions 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 and its consequences or haemodilution could represent a special risk for the patient. Examples of such conditions are:
- decompensated cardiac insufficiency
- arterial hypertension
- oesophageal varices
- pulmonary oedema
- haemorrhagic diathesis
- severe anaemia
- renal and post-renal anuria

The colloid-osmotic effect of human albumin 200 or 250 g/l is approximately four times that of blood plasma.
Therefore, when concentrated albumin is administered, care must be taken to assure adequate hydration of the patient. Patients should be monitored carefully to guard against circulatory overload and hyperhydration.

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 electrolytes status of the patients should be monitored (see the chapter Posology) 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 in recipients.

If large volumes are to be replaced, control of coagulation and haematocrit are necessary. Care must be taken to ensure adequate substitution of other blood constituents (coagulation factors, electrolytes, platelets and erythrocytes).
If the haematocrit drops below 30%, packed red cells should be given in order to maintain the oxygen transport capacity of the blood.
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, jugular vein congestion), or increased blood pressure, raised venous pressure and pulmonary oedema, the infusion is to be stopped immediately.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

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

Incompatibilities

UMAN ALBUMIN must not be mixed with other medicinal products (except the solutions recommended in the chapter "Dose, method and time of administration"), whole blood and packed red cells.

SPECIAL WARNINGS

Pregnancy and lactation

The safety of UMAN ALBUMIN 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.
No animal reproduction studies have been conducted with UMAN ALBUMIN.
However human albumin is a normal constituent of human blood.
In general, particular attention must be paid when a substitution of volume is effected in a pregnant patient.

Viral 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 transmissions with albumin manufactured to European Pharmacopoeia specifications by established processes.

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

Effects on the ability to drive and use machines

No effects on ability to drive and use machines have been observed.

TO BE KEPT OUT OF THE REACH AND SIGHT OF CHILDREN

DOSE, METHOD AND TIME OF ADMINISTRATION

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

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.

UMAN ALBUMIN can be administered to premature infants and dialysis patients as the aluminium content of the finished product is not more than 200 µg/l.

Human albumin 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).
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.
Albumin solutions must not be diluted with water for injections as this may cause haemolysis in recipients.
If large volume are administered, the product should be warmed to room or body temperature before use.

Overdose

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. Additionally, diuresis or cardiac output should be increased in accordance to the severity of the clinical situation.

UNDESIRABLE EFFECTS

Mild reactions such as flush, urticaria, fever, and nausea occur rarely. These reactions normally disappear rapidly when the infusion rate is slowed down or the infusion is stopped. Very rarely, severe reactions such as shock may occur. In these cases, the infusion should be stopped and an appropriate treatment should be initiated.
For information on viral safety see "Special warning".

Any side effects that have not been described must be communicated to your physician or pharmacist.

EXPIRY

UMAN ALBUMIN in its intact package and stored in compliance with the prescribed conditions has the expiry date reported on the label.

WARNING: do not use the product after the expiry date reported on the label.

Special precautions for storage

Do not store the product above 30°C.
Keep the vial in the outer carton in order to protect from light.
Do not freeze.
The storage conditions should be strictly followed.

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.
Once the container has been opened, the contents should be used immediately.
Any unused product should be disposed of in accordance with local requirements.

DATE OF APPROVAL OF THE PACKAGE LEAFLET BY THE MEDICINES AGENCY: Decree of the Italian Medicines Agency of January 2007.