

PRODUCT INFORMATION

Albumex[®] 20 NexGen

(Human albumin) – Solution for intravenous infusion

1 NAME OF THE MEDICINE

Human albumin

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Human Albumin 20% (200 g/L)

Albumex[®] 20 NexGen is a solution containing 200 g/L of total protein of which at least 96% is human albumin. Albumex[®] 20 NexGen is hyperoncotic to normal plasma. It has a nominal osmolality of 258 mOsm/kg, is isotonic and the pH is 6.7–7.3.

Albumex[®] 20 NexGen is manufactured from human plasma collected by Pusat Darah Negara, Malaysia.

One litre of Albumex[®] 20 NexGen also contains 16 mmol of sodium acetyltryptophanate and 16 mmol of sodium octanoate. Sodium chloride is added to give a sodium content of 140 mmol/L.

Albumex[®] 20 NexGen also contains Water for Injections.

3 PHARMACEUTICAL FORM

Solution for intravenous infusion.

Albumex[®] 20 NexGen is a clear, slightly viscous liquid; it is almost colourless, yellow, amber or green.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

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

4.2 DOSE 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 or protein losses. Measurements of the circulating blood volume, and not just of the plasma albumin level, should be used to determine the dose required.

Human albumin should be administered under careful haemodynamic monitoring; the parameters include:

- arterial blood pressure and heart rate,
- central venous pressure,
- pulmonary artery wedge pressure,
- urine output,
- electrolytes,
- haematocrit / haemoglobin.

Paediatric population

The posology in children and adolescents (0 - 18 years) should be adjusted to the patient's individual requirements.

Method of administration

Albumex[®] 20 NexGen is administered intravenously. The product is ready for use and can be administered as supplied, either directly or it can first be diluted with an isotonic solution (e.g. 5% glucose or 0.9% sodium chloride).

NOTE: Albumex[®] 20 NexGen contains no antimicrobial preservative. It must, therefore, be used immediately after opening the vial. Use in one patient on one occasion only. Any unused solution should be discarded appropriately.

Albumex[®] 20 NexGen is a clear, slightly viscous liquid; it is almost colourless, yellow, amber or green. 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.

Albumex[®] 20 NexGen is packaged in a glass vial that must be vented during use.

Albumex[®] 20 NexGen 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, but should normally not exceed 1 - 2 ml/min.

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 if the solution has been frozen.

4.3 CONTRAINDICATIONS

Hypersensitivity to albumin preparations or to any of the excipients (see section “Composition”).

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Suspicion of allergic or anaphylactic type reactions requires immediate discontinuation of the infusion. 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
- hypertension
- oesophageal varices
- pulmonary oedema
- haemorrhagic diathesis
- severe anaemia
- renal and post-renal anuria.

The colloid-osmotic effect of human albumin 200 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 electrolyte status of the patient should be monitored (see section 4.2 Dose and method of administration) and appropriate steps taken to restore or maintain the electrolyte balance.

Albumex[®] 20 NexGen must not be diluted with water for injections as this may cause haemolysis 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 infusion rate 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.

Albumex[®] 20 NexGen contains approximately 3.2 mg sodium per mL of solution (140 mmol/L). This should be noted when the product is used in patients requiring sodium restriction.

Pathogen safety

This product is made from human plasma. Products made from human plasma may contain infectious agents such as viruses and theoretically Creutzfeldt-Jakob Disease (CJD) agents, that can cause disease. The risk that such products will transmit an infectious agent has been reduced by screening plasma donors for prior exposure to certain infectious agents and by testing for the presence of certain viral markers.

In addition, the Albumex[®] 20 NexGen manufacturing process includes pasteurisation (60°C for 10 hours) and multiple steps involving ethanol fractionation and depth filtration in the presence of filter aids which contribute to the reduction of pathogens should they be present. The current process and procedures applied in the manufacture of this product are effective against enveloped viruses such as human immunodeficiency virus (HIV), hepatitis B virus (HBV) and hepatitis C virus (HCV), and the non-enveloped virus, hepatitis A virus (HAV) and human parvovirus B19.

Despite these measures, such products may still potentially transmit disease. There is also the possibility that other known or unknown infectious agents may be present in such products.

Vaccination for patients in receipt of medicinal products from human plasma should be considered where appropriate.

It is strongly recommended that every time that Albumex[®] 20 NexGen is administered to a patient, the name and batch number of the product are recorded in order to maintain a link between the patient and the batch of the product.

Use in the elderly

There have been no specific clinical studies of Albumex[®] 20 NexGen in the elderly.

Paediatric use

There have been no specific clinical studies of Albumex[®] 20 NexGen in children.

Effects on laboratory tests

Human albumin is an endogenous plasma protein so no specific effects on laboratory tests are anticipated.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

No specific interactions between human albumin and other medicinal products are known. However, it should be borne in mind that the effects of medicinal products that bind strongly to albumin may be influenced by changes in the albumin level.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No studies examining the effect of Albumex[®] 20 NexGen on fertility have been conducted.

Use in pregnancy

Reproductive toxicity studies with Albumex[®] 20 NexGen in animals have not been conducted.

The use of Albumex[®] 20 NexGen in human pregnancy has not been established in controlled clinical trials; therefore, use in pregnant women only if benefits outweigh risk.

Use in lactation

Like endogenous serum albumin, Albumex[®] 20 NexGen may be excreted in milk. No safety information is available.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

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

4.8 ADVERSE EFFECTS (UNDESIRABLE EFFECTS)

Summary of the safety profile

Mild reactions with human albumin solutions 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 allergic reactions such as anaphylactic shock may occur. In these cases, the infusion should be stopped immediately and an appropriate treatment should be initiated.

Tabulated list of adverse reactions

Table 1 presents the adverse reactions which have been observed with CSL Behring human albumin solutions during the post-marketing phase, according to the MedDRA system organ classification (SOC and Preferred Term Level). As the post-marketing reporting of adverse reactions is voluntary and from a population of uncertain size, it is not possible to reliably estimate the frequency of these reactions. Hence the frequency category ‘not known (cannot be estimated from the available data)’ is used.

Table 1: List of adverse reactions

MedDRA System Organ Class (SOC)	Adverse Reaction	Frequency
Immune system disorders	Hypersensitivity reactions (including anaphylaxis and shock)	Not known
Gastrointestinal disorders	Nausea	Not known
Skin and subcutaneous tissue disorders	Flush, urticaria	Not known
General disorders and administration site conditions	Fever	Not known

For safety information with respect to transmissible agents, see section 4.4 Special warnings and precautions for use -Pathogen safety.

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions [via](#) local reporting mechanism.

4.9 OVERDOSE

Hypervolaemia may occur if the dosage and infusion rate 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.

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

Human albumin accounts quantitatively for more than half of the total protein in the plasma and represents about 10% of the protein synthesis activity of the liver.

Physico-chemical data: human albumin 200 g/L has a hyperoncotic effect.

The most important physiological functions of albumin results from its contribution to oncotic pressure of the blood and transport function. Albumin stabilises circulating blood volume and is a carrier of hormones, enzymes, medicinal products and toxins.

Clinical trials

There have been no company sponsored clinical trials conducted using Albumex® 20 NexGen .

5.2 PHARMACOKINETIC PROPERTIES

Distribution

Under normal conditions, the total exchangeable albumin pool is 4 - 5 g/kg body weight, of which 40 - 45% is present intravascularly and 55 - 60% in the extravascular space. Increased capillary permeability alters albumin kinetics. Abnormal distribution can occur under pathological conditions, e.g. after severe burns and in septic shock.

Elimination

Under normal conditions, the average half-life of albumin is about 19 days. The balance between synthesis and breakdown is normally achieved by a feedback mechanism. Elimination is predominantly intracellular and due to lysosomal proteases. In healthy subjects, less than 10% of infused albumin leaves the intravascular compartment during the first 2 hours following infusion. There is considerable individual variation in the effect on plasma volume. In some patients the plasma volume remains increased for several hours. However, in critically ill patients, albumin can leak out of the vascular system in substantial amounts at an unpredictable rate.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

No genotoxicity studies have been conducted with Albumex® 20 NexGen .

Carcinogenicity

No carcinogenicity studies have been conducted with Albumex® 20 NexGen .

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Refer to Section 2 Qualitative and quantitative composition.

6.2 INCOMPATIBILITIES

Albumex[®] 20 NexGen must not be mixed with any other medicinal products, including whole blood, packed red cells, or other albumins.

6.3 SHELF LIFE

36 months.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 30°C (Do not freeze). Protect from light. Do not use after the expiry date.

6.5 INSTRUCTIONS FOR USE AND HANDLING

Albumex[®] 20 NexGen is administered intravenously. Albumin solutions must not be diluted with water for injections as this may cause haemolysis in patients). If large volumes are administered, the product should be warmed to room or body temperature before use. The solution is clear and slightly viscous. Do not use infusion solutions that 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 or waste material should be disposed of in accordance with local regulations.

6.6 NATURE AND CONTENTS OF CONTAINER

Albumex[®] 20 NexGen is issued in glass vials in:

One vial of 100 mL contains 20 g of human albumin.

6.7 SPECIAL PRECAUTIONS FOR DISPOSAL

Any unused medicine or waste material should be disposed of in accordance with local requirements.

7 MANUFACTURER

CSL Behring (Australia) Pty Ltd
189–209 Camp Road
Broadmeadows VIC 3047
Australia

Product Registration Holder

Pusat Darah Negara,

Jalan Tun Razak,

50400, Kuala Lumpur

Malaysia

8 DATE OF REVISION

Nov 2023

® Registered trademark of CSL Behring