VIALEBEX®

200 mg/ml
50 ml - 100 ml

Solution for infusion
Human Albumin Solution

Read all of this leaflet carefully before you start using this medicine.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.

VIALEBEX® 200 mg/ml, solution for infusion.

• The active substance is human albumin (200 mg/ml, i.e. 20%).
Each 100 ml vial contains 20 g of human albumin.
Each 50 ml vial contains 10 g of human albumin.
The solution contains 200 mg/ml of protein of which at least 95% is human albumin.

• The other ingredients are sodium chloride, sodium caprylate and water for injections.

MARKETING AUTHORISATION HOLDER

LABORATOIRE FRANÇAIS DU FRACTIONNEMENT ET DES BIOTECHNOLOGIES
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1. WHAT VIALEBEX® IS AND WHAT IT IS USED FOR

VIALEBEX® is a solution for infusion in vials of 50 ml and 100 ml.

Pharmacotherapeutic group : plasma substitutes and plasma protein fractions
ATC code : B05AA01, Albumin.

VIALEBEX® is used for 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.

2. BEFORE YOU USE VIALEBEX®

Do not use VIALEBEX®

• If you are allergic to albumin or any of the other ingredients of VIALEBEX®.

Take special care with VIALEBEX® :

If allergic or anaphylactic-type reactions occur, the infusion should be stopped immediately and appropriate treatment initiated. In case of shock, the 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,
- œsophageal varices,
- pulmonary œdema,
- haemorrhagic diathesis,
- severe anaemia,
- renal and post-renal anuria.

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 mg/ml (20%) human albumin solutions are relatively low in electrolytes compared to the 40-50 mg/ml (4-5%) human albumin solutions. When albumin is given, the electrolyte status of the patient should be monitored 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 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 patient's circulatory situation. At the first clinical signs of cardiovascular overload (headache, dyspnoea, jugular vein congestion), increased blood pressure, raised venous pressure or pulmonary œdema, the infusion is to be stopped immediately.

• When human blood- or plasma-derived products are administered, the risk of transmission of infective agents cannot be totally excluded. This applies also to pathogens of hitherto unknown nature.

However, this risk is reduced by :
- strict donor selection through medical interview of each donor and screening of each donation through testing for major viral markers,
- testing of plasma pools for genomic material of hepatitis C,
- manufacturing processes used for this product, which include viral elimination and/or inactivation treatment, verified by viral validation studies.

The viral removal/inactivation procedures may be of limited value against certain particularly resistant viruses (non-enveloped viruses).

Albumin manufactured to European Pharmacopoeia specifications by established processes has a reassuring viral safety record.

No cases of viral infection have been reported in association with administration of human plasma albumin.

In the interest of patients, it is recommended that, whenever possible, every time that VIALEBEX® is administered to them, the name and batch number of the product is recorded.

VIALEBEX® contains 280 mg of sodium per 100 ml vial and 140 mg per 50 ml which should be taken into account in case of a sodium restricted diet and it does not contain more than 200 µg/l of aluminium.

Pregnancy and breast-feeding

The safety of VIALEBEX® 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 fœtus and the neonate are to be expected.

Experimental animal studies are insufficient to assess the safety with respect to reproduction, development of the embryo or fœtus, the course of gestation and peri- and postnatal development.
However, human albumin is a normal constituent of human blood.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

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

Important information about some of the ingredients of VIALEBEX®.

Excipients with notorious effects: sodium salts (sodium chloride, sodium caprylate).

Using other medicines

No drug interactions with human albumin have been reported to date.

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

3. HOW TO USE VIALEBEX®

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 pressure,
- urine output,
- electrolyte,
- haematocrit/haemoglobin.

This product is suitable for premature infants and dialysis patients.

If you have the impression that the effect of VIALEBEX® is too strong or too weak, talk to your doctor or pharmacist.

Method of administration

The solution can be directly administered by the intravenous route or it can also be diluted in an isotonic solution (eg. 50 mg/ml (5%) glucose or 9 mg/ml (0.9%) sodium chloride).

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.

The solution should be clear or slightly opalescent; 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.

Once the container has been opened, the contents should be used immediately.

Any unused product should be disposed of in accordance with local requirements.

Overdose

Hypervolaemia (increase in volume of circulating blood) 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), increased blood pressure, raised central venous pressure or pulmonary œdema (infiltration of liquid in the lungs), the infusion should be stopped immediately and the patient's haemodynamic parameters carefully monitored.

Immediately contact your doctor or pharmacist.

If you forget to use VIALEBEX® :

Do not take a double dose to make up for forgotten individual doses.

4. POSSIBLE SIDE EFFECTS

Like all medicines, VIALEBEX® can have side 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.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. STORING VIALEBEX®

Do not store above 25°C. Do not freeze. Store in the original package in order to protect from light.

Do not use after the expiry date stated on the label and carton.

Do not use any solution which is cloudy or in which a deposit has formed.

Keep out of the reach and sight of children.

This leaflet was last approved on the 10th December 2004.

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