Albunin (Human) 25%, USP
Albuted™ 25

DESCRIPTION
Albunin (Human) 25%, USP (Albuted™ 25) is made from pooled human venous plasma using the Coon cold ethanol precipitation process. The albumin concentration may be perfomed by another licensed manufacturer. The product is prepared in accordance with the applicable requirements established by the U.S. Food and Drug Administration (FDA).

Albuted 25 is a 25% sterile solution of albumin in an aqueous diluent. The preparation is stabilized with 0.02 M sodium phosphate buffer, pH 7.0. Albuted 25 is such that it will draw approximately a further 70 mL of fluid from the extracellular space, provided the patient is normally hydrated interstitially or there is interstitial edema. If the patient is dehydrated, additional crystalloids must be given, or alternatively, Albumin (Human) 5%, USP (Albuted™ 5) should be used. The patient’s hemodynamic response should be monitored and the use of excess albumin against a predetermined goal observed. The total dose should not exceed the level of extravascular fluid that can be removed from the patient in a single session of extracorporeal blood purification.

CLINICAL PHARMACOLOGY
Each 20 mL vial of Albuted 25 supplies the oncotic equivalent of approximately 100 mL albumin plasma; 50 mL supplies the oncotic equivalent of approximately 250 mL plasma.

Albuted 25 is free of carcinoembryonic antigen (CEA), rheumatoid factor, and heparin. The product also contains no pyrogens or endotoxins. Albuted 25 is a transport protein and it may be useful in severe hemolytic disease in the neonate who is awaiting exchange transfusion. The infused albumin may reduce the level of free bilirubin in the blood. This could also be of importance in acute liver failure where albumin might serve the double purpose of supporting the colloid osmotic pressure as well as binding excessive plasma bilirubin.

Emergency Treatment of Hypovolemic Shock
Albuted 25 is hypertoncotic and on intravenous infusion will expand the plasma volume by an additional 50 to 70 mL for every 100 mL of the volume actually administered, by withdrawing fluid from the interstitial spaces, provided the patient is normally hydrated interstitially or there is interstitial edema. If the patient is dehydrated, additional crystalloids must be given, or alternatively, Albumin (Human) 5%, USP (Albuted™ 5) should be used. If the patient’s hemodynamic response should be monitored and the use of excess albumin against a predetermined goal observed. The total dose should not exceed the level of extravascular fluid that can be removed from the patient in a single session of extracorporeal blood purification.

Indications and Usage
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Situations in Which Albumin Administration can be helpful include:
- **Acute Liver Failure**: Albumin may be required to avoid excessive hypoproteinemia, during certain types of exchange transfusion, for prior extended volumes of crystalloids are infused to restore the depleted extracellular fluid volume. Beyond 24 hours Albuted 25 can be used to maintain plasma colloid osmotic pressure.
- **Hypoproteinemia Without Or Without Edema**: During major surgery, patients can lose over half of their circulating albumin with the attendant complications of oncotic deficit.
- **Removal of Ascitic Fluid**: From a patient with cirrhosis may cause change in cardiovascular function and even result in cardiopulmonary shock. In this situation, the use of an albumin infusion may be required to support the blood volume. Albuted 25 is a transport protein and it may be used in severe hemolytic disease in the neonate who is awaiting exchange transfusion. The infused albumin may reduce the level of free bilirubin in the blood. This could also be of importance in acute liver failure where albumin might serve the double purpose of supporting the colloid osmotic pressure as well as binding excessive plasma bilirubin.

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certain viruses, by testing for the presence of certain current virus infections, and by inactivating and/or removing certain viruses. Despite these measures, such products can still potentially transmit disease. This is why it is possible that recipients of infected or contaminated blood products or patients from whom such blood products have been transmitted by this product should be reported by the physician or other healthcare provider to Talecris Biotherapeutics, Inc.

The physician should discuss the risks and benefits of this product with the patient, before prescribing or giving the product.

As with any hyperoncotic protein solution likely to be administered in large volumes, severe hemolysis and acute allergic reactions may result. Such reactions may be caused by the extravasation of red blood cells or an immunologic reaction as a result of a high protein concentration. (Human). 25%. Acceptable diluents include 0.9% Sodium Chloride or 5% Dextrose in Water. Please refer to the DOSAGE AND ADMINISTRATION for further information on drug administration. Solutions which have been frozen should not be used. Do not use if turbid. Do not begin administration more than 1 hour after the container has been opened. Partial vials should be discarded. Vials should not be cracked or which have been previously entered or damaged should not be used. As this may have allowed the entry of microorganisms. Albumin (Human) 25%, USP (Albuked®) contains no preservatives.

PRECAUTIONS

General

Patients should always be monitored carefully in order to guard against the possibility of circulatory overload. Albuked 25 is hyperoncotic; therefore, in the presence of dehydration, albumin must be given with or followed by adequate volumes of fluid. In hemotherapeutic the administration of albumin should be supplemented by the transfusion of whole blood to treat hypovolemia (see section “Dosage,” method of administration, and biological differences in individual patients. Because of such as 5% Dextrose in Water. Albuked 25 should only be administered undiluted or diluted in 0.9% Sodium Chloride solution or 5% Dextrose in Water. The rapid rise in blood pressure which may follow the administration of a colloid with a positive oncotic activity necessitates careful observation to detect and treat severe blood vessels which may not be at the lower blood pressure.

Drug Interactions

Albuked 25 is compatible with whole blood, packed red cells, as well as the standard carbohydrate and electrolyte solutions intended for intravenous use. It should, however, not be mixed with protein hydrolysates, amino acid solutions nor those containing alcohol.

Hypovolemic Shock

During use.

DOSE AND ADMINISTRATION

Albuked 25 should always be administered by intravenous infusion. Albuvin 25 may be administered either undiluted in 0.9% Sodium Chloride solution (5%) or sodium solution (10%) or Albuked 25 may only be administered either undiluted or diluted in a sodium-free aqueous solution such as Dextrose in Water. A number of factors beyond our control could restrict the efficacy of this product or even result in an ill effect following its use. These include improper storage and handling of the product after it leaves our hands, dosage, method of administration, and biological differences in individual patients. Because of such factors, it is important that this product be stored properly and that the directions be followed carefully during use.

Hyporenicol Shock—For treatment of hyporenicic shock, the volume administered and the speed of injection should be adapted to the respiration, pulse and blood pressure.

Bums—After a burn injury (usually beyond 24 hours) there is a close correlation between the amount of fluid required and the degree of burn in plasma colloid osmotic pressure. The aim should be to maintain the plasma albumin concentration in the region of 2.5 g per 100 mL with a plasma oncotic pressure of 20 mm Hg for an adequate albumin concentration of 5.2 g per 100 mL only. This is best achieved by the intravenous administration of Albuked 25. The duration of therapy is decided by the physician on clinical grounds. During the treatment and/or administering it to the patient.

Pregnancy Category

Any production studies have not been conducted with Albuked 25. It is also not known whether Albuked 25 can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Albuked 25 should be given to pregnant women only if clearly needed.

Pediatric Use

Safety and effectiveness in the pediatric population have not been established.

ADVERSE REACTIONS

Adverse reactions to albumin are rare. Such reactions may be allergic in nature or due to high plasma protein level, or excessive albumin infusion. Allergic manifestations include urticaria, chills, fever, and changes in respiration, pulse and blood pressure.

DOSE AND ADMINISTRATION

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Storage

Store at room temperature not exceeding 30°C (86°F). Do not freeze. Do not use after expiration date.

CAUTION

R only

Federal U.S. law prohibits dispensing without prescription.

REFERENCES


13. Talecris Biotherapeutics, Inc. [1-800-520-2807].


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