

PRODUCT MONOGRAPH

PLASBUMIN[®]-5

Albumin (Human) 5%, USP

Intravenous Solution, 5%

Manufacturer's Standard

Plasma Substitute/Blood Derivative

Manufactured by:
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PLASBUMIN[®]-5

Albumin (Human) 5%, USP

PART I: HEALTH PROFESSIONAL INFORMATION

SUMMARY PRODUCT INFORMATION

Table 1 – Product Information Summary

Route of Administration	Dosage Form, Strength	Clinically Relevant Nonmedicinal Ingredients
Intravenous injection	Intravenous solution, 5%	<i>For a complete listing see DOSAGE FORMS, COMPOSITION AND PACKAGING section.</i>

DESCRIPTION

PLASBUMIN[®]-5 (Albumin [Human] 5%, USP) is a 5% sterile solution of albumin in an aqueous diluent. The preparation is stabilized with sodium caprylate (0.08 mmol/g albumin) and acetyltryptophan (0.08 mmol/g albumin). The approximate sodium content of the product is 130 to 160 mEq/L. It has a low aluminum content ($\leq 200 \mu\text{g/L}$), and contains no preservatives. PLASBUMIN[®]-5 must be administered intravenously. It is a clear, slightly viscous liquid, which can range from almost colorless, to yellow, amber or green.

PLASBUMIN[®]-5 is made from pooled human venous plasma using the Cohn cold ethanol fractionation process. It is prepared in accordance with the applicable requirements established by the U.S. Food and Drug Administration.

INDICATIONS AND CLINICAL USE

The oncotic and colloid properties of PLASBUMIN[®]-5 are used to restore and maintain circulating blood volume, when needed, and when the use of a colloid is appropriate. The choice of PLASBUMIN[®]-5 over artificial colloid or crystalloid solutions will depend on the clinical situation of the individual patient, according to current therapeutic guidelines and recommendations.

PLASBUMIN[®]-5 is primarily used in the treatment of shock associated with hemorrhage, surgery, trauma, burns, and bacteremia (1,2).

Emergency Treatment of Hypovolemic Shock

PLASBUMIN[®]-5 is iso-oncotic with normal plasma and on intravenous infusion will expand the circulating blood volume by an amount approximately equal to the volume infused. In conditions associated mainly with a volume deficit, albumin is best administered as a 5% solution (PLASBUMIN[®]-5); but where there is an oncotic deficit, PLASBUMIN[®]-25 may be preferred. This is also an important consideration where the treatment of the shock state has been delayed. If PLASBUMIN[®]-25 is used, appropriate additional crystalloid should be administered (1,2).

Crystalloid solutions in volumes several times greater than that of PLASBUMIN[®]-5 may be effective in treating shock in younger individuals who have no preexisting illness at the time of the incident. Older patients, especially those with preexisting debilitating conditions, or those in whom the shock is caused by a medical disorder, or where the state of shock has existed for some time before active therapy could be instituted, may not tolerate hypoalbuminemia as well (1,2).

Removal of ascitic fluid from a patient with cirrhosis may cause changes in cardiovascular function and even result in hypovolemic shock. In such circumstances, the use of albumin infusion may be required to support the blood volume (1,2).

Burn Therapy

An optimal therapeutic regimen with respect to the administration of colloids, crystalloids, and water following extensive burns has not been established. During the first 24 hours after sustaining thermal injury, large volumes of crystalloids are infused to restore the depleted extracellular fluid volume. Beyond 24 hours PLASBUMIN[®]-25 may be preferred for this purpose (1,2).

Cardiopulmonary Bypass

With the relatively small priming volume required with modern pumps, preoperative dilution of the blood using albumin and crystalloid has been shown to be safe and well-tolerated. Although the limit to which the hematocrit and plasma protein concentration can be safely lowered has not been defined, it is common practice to adjust the albumin and crystalloid pump prime to achieve a hematocrit of 20% and a plasma albumin concentration of 2.5 g per 100 mL in the patient (1,2).

Acute Liver Failure

In the uncommon situation of rapid loss of liver function, with or without coma, administration of albumin may serve the double purpose of supporting the colloid osmotic pressure of the plasma as well as binding excess plasma bilirubin (1,2).

Sequestration of Protein Rich Fluids

This occurs in such conditions as acute peritonitis, pancreatitis, mediastinitis, and extensive cellulitis. The magnitude of loss into the third space may require treatment of reduced volume or oncotic activity with an infusion of albumin (3).

Situations in Which Albumin Administration is Not Warranted

In chronic nephrosis, infused albumin is promptly excreted by the kidneys with no relief of the chronic edema or effect on the underlying renal lesion. It is of occasional use in the rapid "priming" diuresis of nephrosis. Similarly, in hypoproteinemic states associated with chronic cirrhosis, malabsorption, protein losing enteropathies, pancreatic insufficiency, and undernutrition, the infusion of albumin as a source of protein nutrition is not justified (1,2).

CONTRAINDICATIONS

- PLASBUMIN[®]-5 should not be given to patients who are hypersensitive to albumin or to any ingredient in the formulation or component of the container. For a complete listing, see the DOSAGE FORMS, COMPOSITION AND PACKAGING section.
- PLASBUMIN[®]-5 should not be given to patients at special risk of developing circulatory overload (i.e., those with a history of congestive cardiac failure, renal insufficiency or stabilized chronic anemia).

WARNINGS AND PRECAUTIONS

General

PLASBUMIN[®]-5 is made from human plasma. Products made from human plasma may contain infectious agents, such as viruses, 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 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. There is also the possibility that unknown infectious agents may be present in such products. Individuals who receive infusions of blood or plasma products may develop signs and/or symptoms of some viral infections, particularly hepatitis C. ALL infections thought by a physician possibly to have been transmitted by this product should be reported by the physician or other healthcare provider to Grifols Canada Ltd. [1-866-482-5226].

Albumin is a derivative of human blood. Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases. A theoretical risk for transmission of Creutzfeldt-Jakob Disease (CJD), including variant Creutzfeldt-Jakob disease (vCJD), also is considered extremely remote. No cases of transmission of viral diseases or CJD, including vCJD, have ever been identified for albumin (4,5,10).

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

PLASBUMIN[®]-5 must not be diluted with sterile water for injection as this may cause hemolysis and acute renal failure in recipients (see DOSAGE AND ADMINISTRATION).

Blood coagulation parameters, the hematocrit and serum electrolytes should be monitored when a large volume of PLASBUMIN[®]-5 solution is administered.

Patients should always be monitored carefully in order to guard against the possibility of circulatory overload. PLASBUMIN[®]-5 is iso-oncotic with normal plasma and will not tend to aggravate tissue dehydration. Appropriate additional crystalloids should be administered, if required by the patient, to maintain normal fluid balance.

In hemorrhage the administration of albumin should be supplemented by the transfusion of whole blood to treat the relative anemia associated with hemodilution (6). When circulating blood volume has been reduced, hemodilution following the administration of albumin persists for many hours. In patients with a normal blood volume, hemodilution lasts for a much shorter period (7-9).

The rapid rise in blood pressure which may follow the administration of a colloid with positive oncotic activity necessitates careful observation to detect and treat severed blood vessels which may not have bled at the lower blood pressure.

Special Populations

Pregnant and Nursing Women

Animal reproduction studies have not been conducted with PLASBUMIN[®]-5. It is not known whether it can cause harm to the fetus or nursing child. PLASBUMIN[®]-5 should be given to a pregnant or nursing woman only if the benefit outweighs any potential risk.

Pediatrics

The use of PLASBUMIN[®]-5 in children has not been associated with any special or specific hazard, if the dose is appropriate for the child's body weight. However, its use should be carefully evaluated for risk and benefit in pediatric treatment.

ADVERSE REACTIONS

Adverse Drug Reaction Overview

Adverse reactions to albumin are rare. Such reactions may be allergic in nature or due to high plasma protein levels from excessive albumin administration. Allergic manifestations include urticaria, chills, fever, and changes in respiration, pulse and blood pressure. The possibility of an

anaphylactic reaction occurring in association with albumin is considered extremely rare. In the case of an anaphylactic reaction, discontinue infusion and treat appropriately.

The Cochrane Injuries Group published a meta-analysis (July 1998) in which an increase in mortality was reported in albumin-treated patients compared to patients who had received crystalloids or no treatment. However, the analysis was criticized by many authors, due to substantial methodological concerns (11-16).

In 2001, Wilkes et. al. published a revised meta-analysis, which showed no evidence of excess albumin-associated mortality, but suggested that albumin might actually reduce mortality (12).

The Saline versus Albumin Fluid Evaluation (SAFE) Study (15) reported in the New England Journal of Medicine in May 2004, involving nearly 7,000 critically ill patients, addressed one of the most fundamental and contentious issues in critical care: the value of colloids as opposed to crystalloids in the resuscitation of seriously ill patients. Based on these results, the administration of albumin appears to be safe for up to 28 days in a heterogeneous population of critically ill patients, and may be beneficial in patients with severe sepsis. A greater number of patients with trauma involving brain injury died among those randomly assigned to albumin as opposed to saline (59 of 241 in the albumin group compared to 38 of 251 in the saline group with a relative risk of 1.62 and $p = 0.009$). However, the overall number of these patients was relatively small. The study had insufficient power to detect differences in mortality among the predefined subgroups and the authors warn that the observed difference should be interpreted with caution.

A second review by the Albumin Reviewers of the Cochrane Collaboration, published in October 2004 (16), included the results of the SAFE study and concluded that “there is no evidence that albumin reduces mortality when compared with cheaper alternatives, such as saline”, for patients with hypovolemia or in critically ill patients with burns and hypoalbuminemia.

DRUG INTERACTIONS

Drug-Drug Interactions

PLASBUMIN[®]-5 is compatible with the standard isotonic carbohydrate and electrolyte solutions intended for intravenous use. It should not be mixed with protein hydrolysates, amino acid solutions or solutions containing alcohol. It should also not be mixed with whole blood, packed red cells, and other medicinal products. Specialized references (e.g. Trissel's Handbook of Injectable Drugs) should be consulted for specific compatibility information.

DOSAGE AND ADMINISTRATION

Recommended Dose and Dosage Adjustment

The volume administered should be adapted to the response of the individual patient. The infusion rate must be adjusted to individual requirements, based on initial assessment and monitoring of the patient's status. It should normally not exceed 5 mL/minute.

Hypovolemic Shock

The volume infused should be related to the estimated volume deficit and the speed of administration adapted to the response of the patient.

Burn Therapy

After a burn injury (usually beyond 24 hours) there is a close correlation between the amount of albumin infused and the resultant increase in plasma colloid osmotic pressure. The aim should be to maintain the plasma albumin concentration in the region of $2.5 \text{ g} \pm 0.5 \text{ g}$ per 100 mL with a plasma oncotic pressure of 20 mmHg (equivalent to a total plasma protein concentration of 5.2 g per 100 mL) (1,2). This is best achieved by the intravenous administration of PLASBUMIN[®], usually as PLASBUMIN[®]-25. The duration of therapy is decided by the loss of protein from burned areas and in the urine. In addition, oral or parenteral feeding with amino acids should be initiated, as the long-term administration of albumin should not be considered as a source of nutrition.

Cardiopulmonary Bypass

See INDICATIONS AND CLINICAL USE: Cardiopulmonary Bypass.

Acute Liver Failure

See INDICATIONS AND CLINICAL USE: Acute Liver Failure.

Sequestration of Protein Rich Fluids

See INDICATIONS AND CLINICAL USE: Sequestration of Protein Rich Fluid.

Administration

PLASBUMIN[®]-5 should always be administered by intravenous infusion. The choice between the use of PLASBUMIN[®]-5 and PLASBUMIN[®]-25 depends upon whether or not the patient requires primarily a higher colloid osmotic activity (PLASBUMIN[®]-25). Albumin solutions must not be diluted with sterile water for injection to avoid hemolysis and acute renal failure in recipients (see DRUG INTERACTIONS). Remove seal to expose stopper. Always swab stopper top immediately with a suitable antiseptic prior to entering vial.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

Dispensing pins or needles up to 16 gauge should be used, and should only be inserted within the stopper area delineated by the raised ring. The stopper should be penetrated perpendicular to the plane of the stopper within the ring.

Solutions which have been frozen should not be used. Do not use if turbid. Do not begin administration more than 4 hours after the container has been entered. Partially used vials must be discarded. Vials which are cracked or which have been previously entered or damaged should not be used, as this may have allowed the entry of microorganisms. PLASBUMIN[®]-5 contains no preservative.

THERE EXISTS A RISK OF POTENTIALLY FATAL HEMOLYSIS AND ACUTE RENAL FAILURE FROM THE USE OF STERILE WATER FOR INJECTION AS A DILUENT FOR PLASBUMIN[®]-5. ACCEPTABLE DILUENTS INCLUDE 0.9% SODIUM CHLORIDE OR 5% DEXTROSE IN WATER.

OVERDOSAGE

To date, there have been no reported cases of overdose for PLASBUMIN[®]-5. No data are available in regard to overdose in humans; however, because PLASBUMIN[®]-5 is hyperoncotic, patients should be monitored against the possibility of circulatory overload. If overdose occurs, provide standard supportive treatment as necessary.

Hypervolemia may occur if the dosage and rate of infusion are too high. If hypervolemia is suspected, the infusion should be stopped immediately and the patient's hemodynamic parameters should be carefully monitored.

ACTION AND CLINICAL PHARMACOLOGY

Mechanism of Action

PLASBUMIN[®]-5 is oncologically (colloid osmotic) equivalent volume for volume to normal human plasma.

When administered intravenously to an adequately hydrated subject, the oncotic effect of PLASBUMIN[®]-5 is to expand the circulating blood volume by an amount approximately equal to the volume infused.

Albumin is a transport protein that binds to many substances, including drugs and bilirubin. This could be of importance in acute liver failure where albumin might serve the dual role of supporting plasma oncotic pressure, as well as binding excessive plasma bilirubin (1,2).

STORAGE AND STABILITY

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

The product should be used within 4 hours after the container has been entered.

DOSAGE FORMS, COMPOSITION AND PACKAGING

PLASBUMIN[®]-5 is available in 50 mL (pediatric size), 250 mL, and 500 mL rubber-stoppered vials. Each vial contains albumin in the amounts listed in Table 2.

Table 1 – Available PLASBUMIN[®]-5 Vial Sizes

Size	Grams Albumin
50 mL	2.5
250 mL	12.5
500 mL	25.0

PLASBUMIN[®]-5 is a 5% sterile solution of albumin in an aqueous diluent. The preparation is stabilized with sodium caprylate (0.08 mmol/g albumin) and acetyltryptophan (0.08 mmol/g albumin). The approximate sodium content of the product is 130 to 160 mEq/L. It has a low aluminum content ($\leq 200 \mu\text{g/L}$), and contains no preservative.

PART II: SCIENTIFIC INFORMATION

PHARMACEUTICAL INFORMATION

Drug Substance

Proper name:	PLASBUMIN [®] -5
Common name:	Albumin (Human) 5%, USP

Product Characteristics

PLASBUMIN[®]-5 (Albumin [Human] 5%, USP) is a 5% sterile solution of albumin in an aqueous diluent. PLASBUMIN[®]-5 has a pH of 6.4 to 7.4 and a molecular weight of 66,563 Da. The preparation is stabilized with sodium caprylate (0.08 mmol/g albumin) and acetyltryptophan (0.08 mmol/g albumin). The approximate sodium content of the product is 130 to 160 mEq/L. It has a low aluminum content ($\leq 200 \mu\text{g/L}$), and contains no preservative. PLASBUMIN[®]-5 must be administered intravenously.

Viral Inactivation

In addition to the process relevant virus removal/inactivation steps, each vial of PLASBUMIN[®]-5 is heat treated at 60°C for 10 hours to reduce the possibility of transmission of some viruses, including HIV and the hepatitis viruses.

CLINICAL TRIALS

The clinical effectiveness of Albumin (Human), in the mentioned indications, has been determined through many years of clinical use and is described in a number of published studies and clinical practice guidelines.

DETAILED PHARMACOLOGY

See Product Monograph PART I: ACTION AND CLINICAL PHARMACOLOGY.

Albumin regulates the volume of blood and accounts for 80% of the colloid osmotic pressure of plasma (25-33 mmHg) (17). PLASBUMIN[®]-5 supplies the oncotic equivalent volume for volume to normal human plasma. PLASBUMIN[®]-5 is iso-oncotic with normal plasma and on intravenous infusion will expand the plasma volume by an amount approximately equal to the volume administered. In addition to restoring and maintaining blood volume through its stabilizing effect on the physical environment of blood, albumin also provides benefits as a transport vehicle for metabolites, as a role player in lipid metabolism, and as a protective agent,

binding to toxic waste. Some of the endogenous substances that bind to albumin and are subsequently transported include long chain fatty acids (crucial for lipid metabolism), steroid hormones (bind with low affinity to albumin allowing rapid delivery and release to tissues), peptide hormones, bilirubin (an exogenous toxin delivered to the liver for biliary excretion; also acts as an anti-oxidant when bound to albumin), tryptophan, vitamin D₃, folate, copper, zinc, calcium, magnesium, and chloride (17). For many hormones and vitamins, albumin does not serve as the main transport mechanism but functions as their reservoir, continuously replenishing the more specific transport proteins (17).

The half-life of albumin reported from multiple radiolabeled studies ranges between 14.8 days (using albumin prepared by cold-alcohol Cohn techniques [the method used in the manufacture of PLASBUMIN[®]-5]) to 19.5 days (albumin prepared using gentle fractionation conditions). The degradation of albumin, occurring promptly after removal of albumin from circulation, is first-order with the amount of albumin degraded daily seemingly a function of total body albumin concentration (17). The large organs, the muscle and skin, account for most of the degradation of albumin with the kidney, spleen, and lower intestine being minor contributors as well (17). The end product of albumin degradation is free amino acids which remain available in the body for new protein formation.

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PART III: CONSUMER INFORMATION

PLASBUMIN[®]-5

Albumin (Human) 5%, USP

This leaflet is Part 3 of a three-part "Product Monograph" published when PLASBUMIN[®]-5 was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about PLASBUMIN[®]-5. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

Albumin is a protein manufactured by the liver. It is most abundant in human plasma. Normally it constitutes about 55% of all plasma proteins. Albumin has multiple functions, including transport of many small molecules in the blood, such as bilirubin, calcium, and magnesium. Albumin also binds to toxins and heavy metals, thereby preventing damage they might otherwise cause to your body. One of albumin's major roles is in the maintenance of "osmotic or oncotic pressure" that causes fluid to remain within the blood stream instead of leaking out into the tissues.

Possible causes of a decrease in the level of albumin in the blood include liver or kidney disease or increased loss of albumin from circulation (e.g., due to shock). A diseased liver produces less albumin. In kidney disease, albumin can escape into the urine in large amounts. Severe malnutrition or a very low protein diet can also reduce the albumin level.

If the concentration of albumin gets very low, fluid moves from the blood vessels into the tissues, resulting in swelling in the ankles (edema). This fluid can also accumulate in the abdomen (ascites) and in the lungs (pulmonary edema).

What it does:

PLASBUMIN[®]-5 given by intravenous administration can help restore the fluid balance and help improve the problems that led to the low albumin level.

When it should not be used:

You should not use PLASBUMIN[®]-5 if you are allergic to albumin or to any ingredient in the formulation or component of the container.

You should not use PLASBUMIN[®]-5 if you have a history of the following conditions:

- congestive heart failure (the heart does not pump enough blood to the other organs)
- renal insufficiency (a loss of kidney function)
- stabilized chronic anemia (a decrease in the ability of red blood cells to carry oxygen for a prolonged period)

See also SIDE EFFECTS AND WHAT TO DO ABOUT THEM.

What the medicinal ingredient is:

PLASBUMIN[®]-5 contains human albumin (at a concentration of 5%).

What the nonmedicinal ingredients are:

PLASBUMIN[®]-5 also contains sodium caprylate (at a concentration of 0.08 mmol/g albumin), and acetyltryptophan (at a concentration of 0.08 mmol/g albumin), which act as stabilizers.

What dosage forms it comes in:

PLASBUMIN[®]-5 comes in 50 mL (pediatric size), 250 mL, and 500 mL vials (with rubber stoppers).

WARNINGS AND PRECAUTIONS

PLASBUMIN[®]-5 like other products made from human plasma, part of our blood, may contain viruses or other agents that can cause infection and illness. However, the processes used to make PLASBUMIN[®]-5 are specifically designed with the ability to reduce these agents if they are present. You should discuss the risks and benefits of this product with your healthcare provider.

BEFORE you use PLASBUMIN[®]-5 talk to your doctor or pharmacist if:

- you are pregnant or breastfeeding
- you have had an allergic reaction to albumin or any of the other ingredients in the medicine

- you have had a history of congestive heart failure, renal insufficiency, or stabilized chronic anemia

INTERACTIONS WITH THIS MEDICATION

PLASBUMIN®-5 should not be mixed with protein hydrolysates, amino acid solutions or solutions containing alcohol. PLASBUMIN®-5 should not be mixed with whole blood, packed red cells, and other medicinal products.

See also ABOUT THIS MEDICATION: When it should not be used, and SIDE EFFECTS AND WHAT TO DO ABOUT THEM.

PROPER USE OF THIS MEDICATION

Usual dose

Your doctor will determine the amount of PLASBUMIN®-5 that is right for you and when your treatments should be given. A doctor, nurse or other caregiver trained to give injections will give you your treatment.

Overdose

If you or your healthcare professional suspects that you have received an overdose of PLASBUMIN®-5, additional supportive treatment may be required.

Missed Dose

It is important that you receive PLASBUMIN®-5 as instructed by your healthcare professional. You should consult him/her if a treatment appointment is missed.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects following PLASBUMIN®-5 treatment are rare; however, high plasma protein levels may cause allergic reactions.

Talk with your doctor immediately and stop your treatment if you experience any of these side effects:

- wheezing or trouble breathing
- chest tightness
- severe abdominal cramps
- severe vomiting
- severe diarrhea

- rash or hives (swelling, redness, intense itching, and burning)
- swelling of the lips, other parts of the mouth and throat, eyelids, genitals, hands or feet

This is not a complete list of side effects. For any unexpected effects while taking PLASBUMIN®-5, contact your doctor or pharmacist.

HOW TO STORE IT

PLASBUMIN®-5 should be stored at room temperature not exceeding 30°C (86°F). It should not be frozen or used past the expiration date. The product should be used within 4 hours after the container has been entered.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada through the Canada Vigilance Program collects information on serious and unexpected side effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Canada Vigilance:

By toll-free telephone:	866-234-2345
By toll-free fax:	866-678-6789
Online:	www.healthcanada.gc.ca/medeffect
By email:	CanadaVigilance@hc-sc.gc.ca
By regular mail:	Canada Vigilance National Office Marketed Health Products Safety and Effectiveness Information Bureau Marketed Health Products Directorate Health Products and Food Branch Health Canada Tunney's Pasture, AL 0701C Ottawa ON K1A 0K9

NOTE: Should you require information related to the management of the side effect, please contact your health care provider before notifying Canada Vigilance. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document, plus the full product monograph prepared for health professionals, can be obtained by contacting Grifols Canada Ltd., at 1-866-482-5226.

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