ALBUTEIN- albumin (human) injection, solution
GRIFOLS USA, LLC

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use ALBUTEIN FlexBag 5% safely and effectively. See full prescribing information for ALBUTEIN FlexBag 5%.

ALBUTEIN FlexBag 5% (albumin [human] U.S.P.)
5% solution
Initial U.S. Approval: 1978

INDICATIONS AND USAGE

ALBUTEIN 5% is an albumin solution indicated for:

- Hypovolemia. (1.1)
- Cardiopulmonary bypass procedures. (1.2)
- Hypoalbuminemia. (1.3)
- Plasma exchange. (1.4)

DOSAGE AND ADMINISTRATION

For Intravenous Use Only
Dosage and infusion rate should be adjusted to the patient's individual requirements.

Indication	Dose
Hypovolemia	Adults: Initial dose of 20 g (including renal dialysis). For acute liver failure: initial dose of 12 to 25 g. (2.1)
Cardiopulmonary bypass procedures	Adults: Initial dose of 25 g. (2.1)
Hypoalbuminemia	Adults: 50 to 75 g For pre- and post-operative hypoproteinemia: 50 to 75 g. For burn therapy after the first 24 h: initial dose of 25 g and dose adjustment to maintain plasma protein concentration of 2.5 g per 100 mL. Third space protein loss due to infection: initial dose of 50 to 100 g. (2.1)
Plasma exchange	The dose required depends on the volume of plasma removed during the procedure.

Do not dilute with sterile water for injection as this may cause hemolysis in recipients. (5.6)

DOSAGE FORMS AND STRENGTHS

ALBUTEIN 5% is a solution containing 50 g per L of total protein of which at least 95% is human albumin. (3)

CONTRAINDICATIONS

- Hypersensitivity to albumin preparations or to any of the excipients.
- Severe anemia or cardiac failure with normal or increased intravascular volume. (4)

WARNINGS AND PRECAUTIONS

- Suspicion of allergic or anaphylactic reactions requires immediate discontinuation of the injection and implementation of appropriate medical treatment. (5.1)
- Hypervolemia may occur if the dosage and rate of infusion are not adjusted to the patient's volume status. Use with caution in conditions where hypervolemia and its consequences or hemodilution could represent a special risk to the patient. (5.2)
- Monitor electrolytes, coagulation and hematology parameters, and hemodynamic status when albumin is given. (5.3, 5.4, 5.5)
- Do not dilute with sterile water for injection. (5.6)
- Albumin is a derivative of human blood. Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk of transmission of viral diseases and variant Creutzfeldt-

Jakob disease (vCJD). There is a theoretical risk for transmission of Creutzfeldt-Jakob disease (CJD), but if that risk actually exists, the risk of transmission would also be considered extremely remote. No cases of transmission of viral diseases, CJD or vCJD have ever been identified for ALBUTEIN 5%. (5.7)

ADVERSE REACTIONS

The most common adverse reactions are anaphylactoid type reactions. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Grifols Biologicals LLC at 1-888-GRIFOLS (1-888-474-3657) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 3/2025

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

1.1 Hypovolemia

For restoration and maintenance of circulating blood volume where hypovolemia is demonstrated and colloid use is appropriate. When hypovolemia is long standing and hypoalbuminemia exists accompanied by adequate hydration or edema, 20-25% albumin solutions should be used.[1,2,3]

Acute liver failure is a special situation in which both hypovolemia and hypoalbuminemia can be present. ALBUTEIN 5% can be used in such cases.[1]

ALBUTEIN 5% may be of value in the treatment of shock or hypotension in renal dialysis patients.[1]

1.2 Cardiopulmonary Bypass Procedures (Treatment Adjunct)

Preoperative dilution of blood using albumin and crystalloid can be used in cardiopulmonary bypass procedures. Albumin also may be used in the priming fluid.[4,5,6]

1.3 Hypoalbuminemia

ALBUTEIN 5% may be indicated for subjects with hypoalbuminemia who are critically ill and/or actively bleeding. When albumin deficit is the result of excessive protein loss, the effect of ALBUTEIN 5% administration will be temporary unless the underlying disorder is reversed.[7,8,9] Septic patients and patients undergoing major surgery may lose more than half of their circulating plasma volume.[1,10] Treatment with ALBUTEIN 5% may be of value in such cases, especially when plasma colloid oncotic pressure is abnormally low.[1]

In the first 24 hours after thermal injury, large volumes of crystalloids are infused to restore the depleted extracellular fluid volume. Beyond 24 hours, ALBUTEIN 5% can be used to maintain plasma colloid osmotic pressure.[2,11,12] Protein loss from the third space due to infection (acute peritonitis, pancreatitis, mediastinitis or extensive cellulitis) may require treatment with an infusion of albumin.[13,14]

1.4 Plasma Exchange

ALBUTEIN 5% may be used as a replacement fluid during therapeutic Plasma Exchange treatments.[15]

2 DOSAGE AND ADMINISTRATION

For Intravenous Use Only

2.1 Dosage

Adjust the concentration, dosage and infusion rate of the albumin preparation to the patient's individual requirements.

The dose required depends on the patient's body weight, severity of injury/illness and on continuing fluid and protein losses. Use adequacy of circulating blood volume, not plasma albumin levels, to determine the dose required.

Indication	**Dose**
Hypovolemia	Adults: Initial dose of 20 g. If hemodynamic stability is not achieved within 15 to 30 minutes, an additional dose may be given. Hemodilution may follow administration of ALBUTEIN 5%. Anemia resulting from hemorrhage should be corrected by administration of compatible red blood cells or compatible whole blood. For acute liver failure: initial dose of 12 to 25 g. An infusion rate of 1-2 mL per minute is usually indicated. For renal dialysis, the initial dose should not exceed 20 g and patients should be carefully observed for signs of fluid overload.
Cardiopulmonary bypass procedures	Adults: Initial dose of 25 g. Additional amounts may be administered as clinically indicated.
Hypoalbuminemia	Adults: 50 to 75 g For pre- and post-operative hypoproteinemia: 50 to 75 g. In burns, therapy usually starts with administration of large volumes of crystalloid solution to maintain plasma volume. After 24 hours: initial dose of 25 g and dose adjustment to maintain plasma protein concentration of 2.5 g per 100 mL or a serum protein concentration of 5.2 g per 100 mL. Third space protein loss due to infection: initial dose of 50 to 100 g. An infusion rate of 1-2 mL per minute is usually indicated in the absence of shock. Treatment should always be guided by hemodynamic response.
Plasma exchange	The dosage and infusion rate of ALBUTEIN 5% infused should be titrated to the volume of plasma removed during the procedure.

2.2 Administration

Intravenous use only

- Some moisture or condensation may be observed in the protective overwrap. This is normal and does not affect the quality or safety of the albumin solution.
- Check the inner bag for any leaks prior to use by squeezing it firmly. If leaks are detected, discard the solution.

- ALBUTEIN 5% is a clear and slightly viscous solution. Visually inspect for particulate matter and discoloration prior to administration. Do not use if the solution is turbid, if there is sediment in the container, or if the seal is broken.
- Warm product to room temperature before use if large volumes are administered.
- Do not add supplementary medication.
- Do not dilute with sterile water for injection [see *Warnings and Precautions (5.6)].*
- ALBUTEIN 5% contains no preservatives. Once open, the product should be used within four hours. Discard unused portion.
- For single use. Any unused solution must be discarded.
- Adjust the infusion rate to the individual circumstances and the indication. In plasma exchange, adjust the infusion rate to the rate of plasma removal.

CAUTION: Do not use bags in series connections. Such use could result in air embolism due to residual air being drawn from the primary bag before the administration of the fluid from the secondary bag is complete.

1. After checking that protective overwrap is not damaged, remove it by tearing the slots at either end (refer to Figure 1).

2. Suspend the inner bag from the eyelet support (refer to Figure 2).

3. Holding the protective safety shield at the infusion port of the inner bag with one hand, use the free hand to exert light force to turn the twist-off opening about 90 degrees until it leaves the port (refer to Figure 3).

4. Attach either a non-vented or vented administration set (refer to Figure 4). Adjust the infusion rate to the individual circumstances and the indication. Refer to the complete directions of administration set used.

Figure 1

Figure 2

Figure 3

Figure 4

3 DOSAGE FORMS AND STRENGTHS

ALBUTEIN 5% is a solution containing 50 g per L of total protein of which at least 95% is human albumin.

4 CONTRAINDICATIONS

- Hypersensitivity to albumin preparations or to any of the excipients.
- Severe anemia or cardiac failure with normal or increased intravascular volume.

5 WARNINGS AND PRECAUTIONS

5.1 Hypersensitivity

Suspicion of allergic or anaphylactic reactions requires immediate discontinuation of the infusion and implementation of appropriate medical treatment.

5.2 Hypervolemia/Hemodilution

Hypervolemia may occur if the dosage and rate of infusion are not adjusted to the patient's volume status. At the first clinical signs of fluid overload (headache, dyspnea, jugular venous distention, increased blood pressure), the infusion must be slowed or stopped immediately. Use albumin with caution in conditions where hypervolemia and its consequences or hemodilution could represent a special risk to the patient. Examples of such conditions are:

- Decompensated heart failure
- Hypertension
- Esophageal varices
- Pulmonary edema
- Hemorrhagic diathesis
- Severe anemia
- Renal and post-renal anuria

5.3 Electrolyte Imbalance

Monitor regularly the electrolyte status of the patient and take appropriate steps to restore or maintain the electrolyte balance when albumin is administered.

5.4 Coagulation Abnormalities

Regular monitoring of coagulation and hematology parameters is necessary if comparatively large volumes are to be replaced. Care must be taken to ensure adequate substitution of other blood constituents (coagulation factors, electrolytes, platelets, and erythrocytes).

5.5 Laboratory Monitoring

Monitor regularly hemodynamic parameters during administration of ALBUTEIN 5%; this may include:

- Arterial blood pressure and pulse rate
- Central venous pressure
- Pulmonary artery occlusion pressure
- Urine output
- Electrolytes
- Hematocrit/hemoglobin

5.6 Application Precautions

ALBUTEIN 5% must not be diluted with sterile water for injection as this may cause hemolysis in recipients [see *Dosage and Administration (2.2)*].

5.7 Transmissible Infectious Agents

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 and variant Creutzfeldt-Jakob disease (vCJD). There is a theoretical risk for transmission of Creutzfeldt-Jakob disease (CJD), but if that risk actually exists, the risk of transmission would also be considered extremely remote. No cases of transmission of viral diseases, CJD or vCJD have ever been identified for ALBUTEIN 5%.

6 ADVERSE REACTIONS

The most serious adverse reactions are anaphylactic shock, heart failure and pulmonary edema. The most common adverse reactions are anaphylactoid type reactions.

Adverse reactions to ALBUTEIN 5% normally resolve when the infusion rate is slowed or the infusion is stopped. In case of severe reactions, the infusion is stopped and appropriate treatment initiated.

6.1 Clinical Trials Experience

No clinical studies were done using ALBUTEIN 5%.

6.2 Postmarketing Experience

Because adverse reactions are reported voluntarily post-approval from a population of uncertain size, it is not always possible to reliably estimate their frequency or to establish a causal relationship to product exposure. The following adverse reactions have been identified during post approval use of human albumin, including ALBUTEIN (all strengths) in decreasing order of significance:

- Anaphylactic shock
- Heart failure
- Pulmonary edema
- Hypotension
- Tachycardia
- Vomiting
- Urticaria
- Rash
- Headache
- Chills
- Fever
- Flushing
- Nausea

7 DRUG INTERACTIONS

ALBUTEIN 5% must not be mixed with other medicinal products.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Risk Summary

There is no data with ALBUTEIN 5% use in pregnant women to inform a drug-associated risk. Animal reproduction studies have not been conducted with ALBUTEIN 5%. It is not known whether ALBUTEIN 5% can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. ALBUTEIN 5% should be given to a pregnant woman only if clearly needed. In the U.S. general population, the estimated background risk of major birth defect and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

8.2 Lactation

Risk Summary

There is no information regarding the presence of ALBUTEIN 5% in human milk, the effect on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for ALBUTEIN 5% and any potential adverse effects on the breastfed infant from ALBUTEIN 5%.

8.4 Pediatric Use

No human or animal data. Use only if clearly needed.

8.5 Geriatric Use

No human or animal data. Use only if clearly needed.

11 DESCRIPTION

ALBUTEIN 5% is a sterile, aqueous solution for single dose intravenous administration containing 5% human albumin (weight/volume). ALBUTEIN 5% is prepared by a cold alcohol fractionation method from pooled human plasma obtained from venous blood. The product is stabilized with 0.08 millimole sodium caprylate and 0.08 millimole sodium acetyltryptophanate per gram of protein.

ALBUTEIN 5% is osmotically and isotonically equivalent to an equal volume of normal human plasma.

A liter of ALBUTEIN 5% solution contains 130-160 milliequivalents of sodium ion. The aluminum content of the solution is not more than 200 micrograms per liter during the shelf life of the product. The product contains no preservatives.

ALBUTEIN 5% is manufactured from Source Plasma collected from FDA approved plasmapheresis centers in the United States. ALBUTEIN 5% is heated at 60 °C for ten hours, a process that has the capacity to inactivate viruses.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

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

Human Albumin 5% is almost isooncotic to normal plasma.

The primary physiological function of albumin results from its contribution to plasma colloid oncotic pressure and transport function. Albumin stabilizes circulating blood volume and is a carrier of hormones, enzymes, medicinal products and toxins. Other physiological functions include antioxidant properties, free radical scavenging and capillary membrane integrity.

12.3 Pharmacokinetics

Albumin is distributed throughout the extracellular space and more than 60% of the body albumin pool is located in the extravascular fluid compartment. Albumin has a circulating life span of 15-20 days, with a turnover of approximately 15 g per day.

The balance between synthesis and breakdown is normally achieved by feedback regulation. Elimination is predominantly intracellular and due to lysosome 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 of albumin on plasma volume. In some patients, plasma volume can remain elevated for several hours. In critically ill patients, however, albumin can leak out of the vascular space in substantial amounts at an unpredictable rate.

15 REFERENCES

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16 HOW SUPPLIED/STORAGE AND HANDLING

ALBUTEIN FlexBag 5% is supplied in a single-dose, latex-free, flexible container, free of polyvinyl chloride (PVC), diethylhexyl phthalate (DEHP), or other plasticizers. The protective overwrap on each container is also latex-free, and contains no chloride, PVC or plasticizers. Each container is individually laser-etched with at least the lot number and expiration date.

The following package sizes of ALBUTEIN FlexBag 5% are available in multipacks of either 4 or 2 FlexBags/carton or in singlepacks of 1 FlexBag/carton:

Carton NDC	FlexBag NDC	FlexBags	Fill Size	Grams Protein
68516-5218-4	68516-5218-0	4	250 mL	12.5 g
68516-5219-2	68516-5219-0	2	500 mL	25 g
68516-5218-1	68516-5218-0	1	250 mL	12.5 g
68516-5219-1	68516-5219-0	1	500 mL	25 g

Storage
ALBUTEIN FlexBag 5%, in flexible container, is stable for three years provided the storage temperature does not exceed 30 °C. Protect from freezing. Keep the overwrap intact.

17 PATIENT COUNSELING INFORMATION

This product is usually given in a hospital setting.

Inform patients being treated with ALBUTEIN 5% about the risks and benefits of its use [see *Adverse Reactions (6)*].

Inform patients to immediately report the following signs and symptoms to their physician:

- Allergic or anaphylactic type reactions [see *Warnings and Precautions (5.1)*].
- Cardiovascular overload (e.g., headache, dyspnea and jugular venous distention) [see *Warnings and Precautions (5.2)*].
- Increased blood pressure, raised venous pressure and pulmonary edema [see *Warnings and Precautions (5.2)*].

Inform patients that ALBUTEIN 5% is a derivative of human plasma and may contain infectious agents that cause disease (e.g., viruses, and theoretically, the CJD agent). Inform patients that the risk that ALBUTEIN 5% may transmit an infectious agent has been reduced by screening plasma donors for prior exposure to certain viruses, by testing the donated plasma for certain viral agents and by the introduction of steps with capacity for the inactivation and/or removal of certain viruses during the manufacturing process [see *Warnings and Precautions (5.7)*].

Manufactured by:

Grifols Biologicals LLC
5555 Valley Boulevard
Los Angeles, CA 90032, U.S.A.
U. S. License No. 1694

3068288

Principal Display Panel – 250 mL Bag Label

NDC 68516-5218-0

Albumin (Human) U.S.P.
ALBUTEIN FlexBag® 5%

12.5 g / 250 mL
5%

Rx only

Contents: Each 250 mL contains 12.5 grams Albumin (Human) in aqueous diluent, and is osmotically and isotonically equivalent to an equal volume of normal human plasma. Sodium range is 130-160 milliequivalents per liter. Stabilized with sodium caprylate and
sodium acetyltryptophanate. Contains no preservatives. Heat-treated at 60 °C for 10 hours.

Instructions: See accompanying Full Prescribing Information.

Precautions: Single-dose container for intravenous administration. Prior to administration, check bag for leaks by squeezing firmly. If leaks are found, discard bag as sterility may be compromised. **Do not use if turbid. Do not begin administration more than four hours after the container has been entered.** Discard
any unused contents and administration devices after use.

Store at temperatures not exceeding 30 °C. Do not allow to freeze. Keep the overwrap intact.

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GRIFOLS

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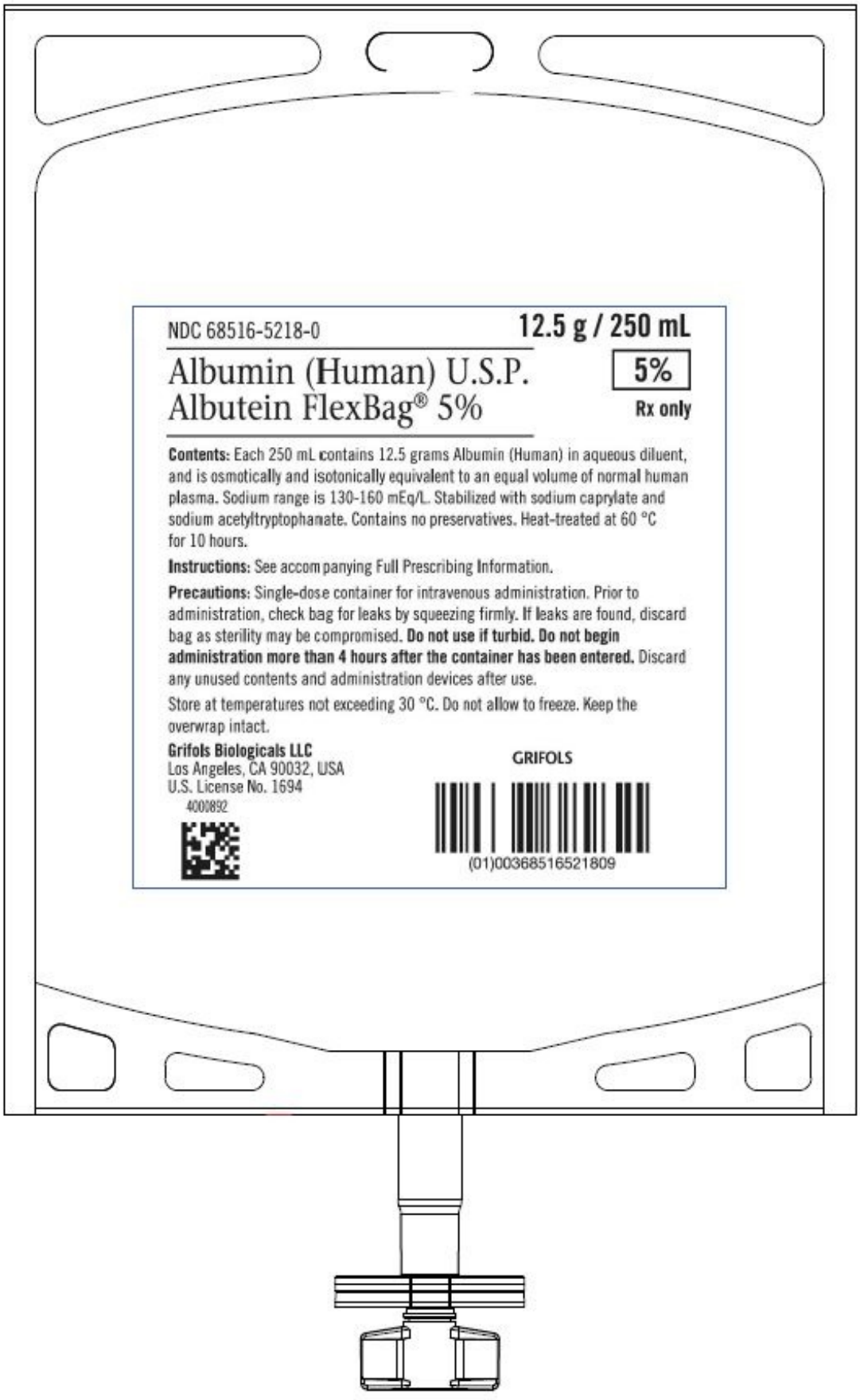

Principal Display Panel – 4 x 250 mL Container Label

NDC 68516-5218-4 12.5 g / 250 mL

Albumin (Human) U.S.P.
Albutein Flexbag® 5%

Solution
5%

4 x 250 mL Single-Dose Containers

Store at temperatures not exceeding 30° C.
Do not allow to freeze. Keep the overwrap intact.

Rx only

Contents:
Each 250 mL contains 12.5 grams Albumin (Human) in aqueous diluent, and is osmotically and
isotonically equivalent to an equal volume of normal human plasma.
Sodium range is 130-160 milliequivalents per liter. Stabilized with 0.08 millimole sodium caprylate and 0.08 millimole sodium acetyltryptophanate per gram of albumin.
Contains no preservatives.
Heat-treated at 60 °C for 10 hours.

Instructions:
The patient and physician should discuss the risks and benefits of this product. For information on
dosage and directions for administration, see accompanying Full Prescribing Information.

Precautions:
Single-dose container for intravenous administration. Prior to administration, check bag for leaks
by squeezing firmly. If leaks are found, discard bag as sterility may be compromised.
**Do not use if turbid. Do not begin administration more than four hours after the container
has been entered.** Discard any unused contents and administration devices after use.
In case of dehydration, administer additional fluids with or immediately following ALBUTEIN®.

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GTIN 00368516521847

LOT XXXXXXXXXX
EXP DDMMMYYYY
SN XXXXXXXXXXXXXXX

Principal Display Panel – 500 mL Bag Label

NDC 68516-5219-0

Albumin (Human) U.S.P.
ALBUTEIN FlexBag® 5%

25 g / 500 mL
5%

Rx only

Contents: Each 500 mL contains 25 grams Albumin (Human) in aqueous diluent, and is osmotically and isotonically equivalent to an equal volume of normal human

plasma. Sodium range is 130-160 mEq/L. Stabilized with sodium caprylate and sodium acetyltryptophganate. Contains no preservatives. Heat-treated at 60 ºC for 10 hours.

Instructions: See accompanying Full Prescribing Information.

Precautions: Single-dose container for intravenous administration. Prior to administration, check bag for leaks by squeezing firmly. If leaks are found, discard bag as sterility may be compromised. **Do not use if turbid. Do not begin administration more than 4 hours after the container has been entered.** Discard
any unused contents and administration devices after use.

Store at temperatures not exceeding 30 ºC. Do not allow to freeze. Keep the overwrap intact.

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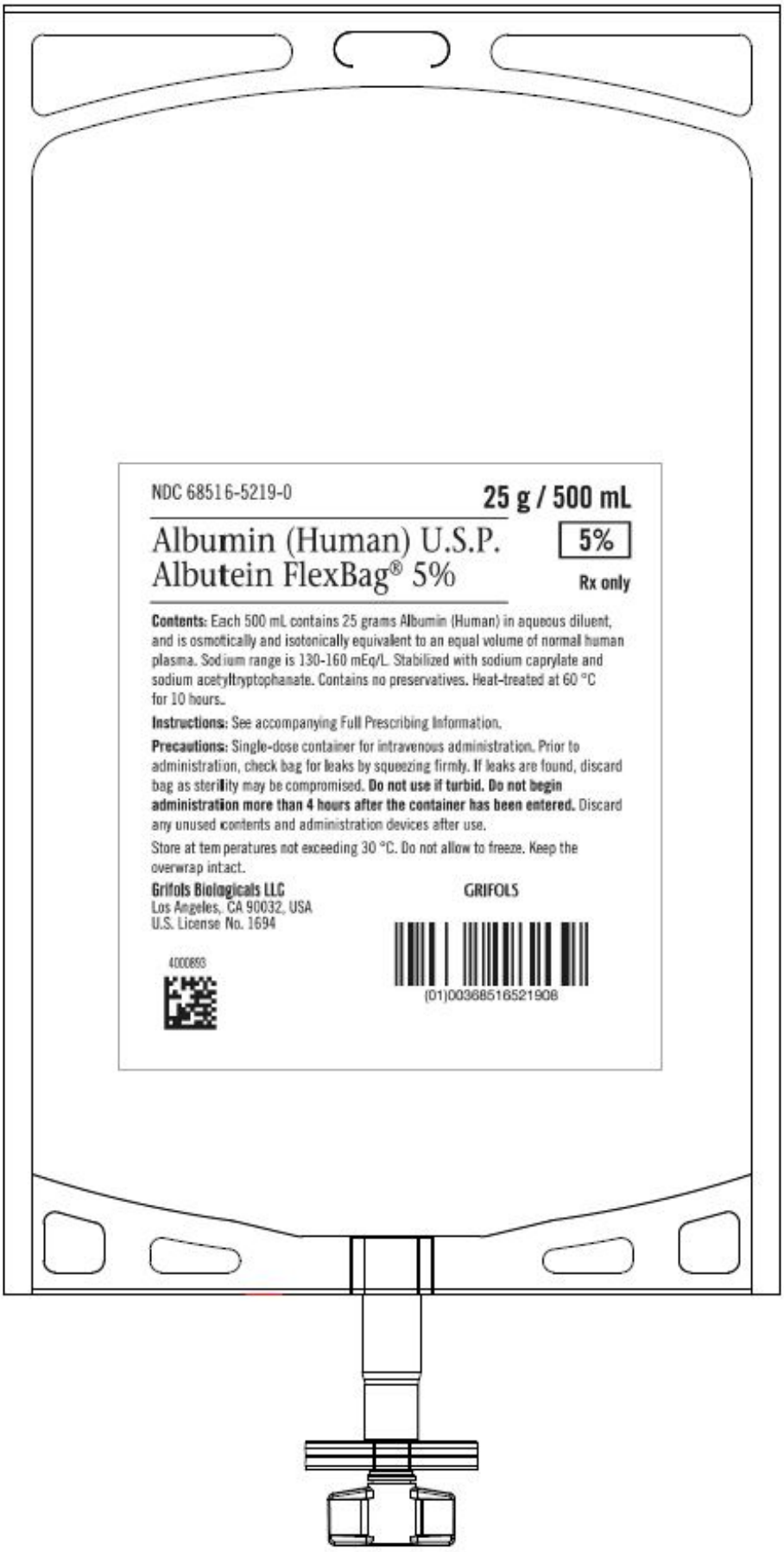

Principal Display Panel – 2 x 500 mL Container Label

GRIFOLS

NDC 68516-5219-2 25 g / 500 mL

Albumin (Human) U.S.P.
Albutein Flexbag® 5%

Solution
5%

2 x 500 mL Single-Dose Containers

Store at temperatures not exceeding 30° C. Do not allow to freeze. Keep the overwrap intact.

Rx only

Contents:
Each 500 mL contains 25 grams Albumin (Human) in aqueous diluent, and is osmotically and
isotonically equivalent to an equal volume of normal human plasma.
Sodium range is 130-160 milliequivalents per liter. Stabilized with 0.08 millimole sodium caprylate
and 0.08 millimole sodium acetyltryptophanate per gram of albumin.
Contains no preservatives.
Heat-treated at 60 °C for 10 hours.

Instructions:
The patient and physician should discuss the risks and benefits of this product. For information on
dosage and directions for administration, see accompanying Full Prescribing Information.

Precautions:
Single-dose container for intravenous administration. Prior to administration, check bag for leaks
by squeezing firmly. If leaks are found, discard bag as sterility may be compromised.
**Do not use if turbid. Do not begin administration more than four hours after the container
has been entered.** Discard any unused contents and administration devices after use.
In case of dehydration, administer additional fluids with or immediately following ALBUTEIN®.

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GTIN 00368516521922
LOT XXXXXXXXXX
EXP DDMMMYYYY

SN XXXXXXXXXXXXXXXX

ALBUTEIN

albumin (human) injection, solution

Product Information			
Product Type	PLASMA DERIVATIVE	**Item Code (Source)**	NDC:68516-5214
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Albumin Human (UNII: ZIF514RVZR) (Albumin Human - UNII:ZIF514RVZR)	Albumin Human	12.5 g in 250 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Sodium Chloride (UNII: 451W47IQ8X)	
Sodium Caprylate (UNII: 9XTM81VK2B)	
N-Acetyl-Dl-Tryptophan Sodium (UNII: 3EN9H0M2FX)	

Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68516-5214-9	4 in 1 CARTON		
1	NDC:68516-5214-7	250 mL in 1 BAG; Type 0: Not a Combination Product		
2	NDC:68516-5214-0	2 in 1 CARTON		
2	NDC:68516-5214-8	500 mL in 1 BAG; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102478	11/08/2021	07/24/2025

ALBUTEIN

albumin (human) injection, solution

Product Information

Product Type	PLASMA DERIVATIVE	**Item Code (Source)**	NDC:68516-5217
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Albumin Human (UNII: ZIF514RVZR) (Albumin Human - UNII:ZIF514RVZR)	Albumin Human	12.5 g in 250 mL

Inactive Ingredients

Ingredient Name	Strength
Sodium Chloride (UNII: 451W47IQ8X)	
Sodium Caprylate (UNII: 9XTM81VK2B)	
N-Acetyl-Dl-Tryptophan Sodium (UNII: 3EN9H0M2FX)	
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68516-5217-5	5 in 1 CARTON		

1	NDC:68516-5217-0	100 mL in 1 BAG; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102478	11/15/2023	12/09/2023

ALBUTEIN

albumin (human) injection, solution

Product Information

Product Type	PLASMA DERIVATIVE	**Item Code (Source)**	NDC:68516-5218
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Albumin Human (UNII: ZIF514RVZR) (Albumin Human - UNII:ZIF514RVZR)	Albumin Human	12.5 g in 250 mL

Inactive Ingredients

Ingredient Name	Strength
Sodium Chloride (UNII: 451W47IQ8X)	
Sodium Caprylate (UNII: 9XTM81VK2B)	
N-Acetyl-Dl-Tryptophan Sodium (UNII: 3EN9H0M2FX)	
Water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68516-5218-4	4 in 1 CARTON		
1	NDC:68516-5218-0	250 mL in 1 BAG; Type 0: Not a Combination Product		
2	NDC:68516-5218-1	1 in 1 CARTON		
2	NDC:68516-5218-0	250 mL in 1 BAG; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102478	11/15/2023	

ALBUTEIN

albumin (human) injection, solution

Product Information			
Product Type	PLASMA DERIVATIVE	**Item Code (Source)**	NDC:68516-5219
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Albumin Human (UNII: ZIF514RVZR) (Albumin Human - UNII:ZIF514RVZR)	Albumin Human	12.5 g in 250 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Sodium Chloride (UNII: 451W47IQ8X)	
Sodium Caprylate (UNII: 9XTM81VK2B)	
N-Acetyl-Dl-Tryptophan Sodium (UNII: 3EN9H0M2FX)	
Water (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:68516-5219-2	2 in 1 CARTON		
1	NDC:68516-5219-0	500 mL in 1 BAG; Type 0: Not a Combination Product		
2	NDC:68516-5219-1	1 in 1 CARTON		
2	NDC:68516-5219-0	500 mL in 1 BAG; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA102478	11/09/2023	

Labeler - GRIFOLS USA, LLC (048987452)

Establishment

Name	Address	ID/FEI	Business Operations
Grifols Biologicals LLC		092694538	manufacture(68516-5219)

Establishment

Name	Address	ID/FEI	Business Operations
Grifols Biologicals LLC		121076871	manufacture(68516-5218, 68516-5219)

Revised: 5/2025

GRIFOLS USA, LLC