

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

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**HIGHLIGHTS OF PRESCRIBING INFORMATION**

**These highlights do not include all the information needed to use ALBUTEIN 5% safely and effectively. See full prescribing information for ALBUTEIN 5%.**

**ALBUTEIN 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.

| <b>Indication</b>                 | <b>Dose</b>   |
|-----------------------------------|---|
| Hypovolemia                       | Adults:<br>Initial dose of 20 g (including renal dialysis).<br>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<br>For pre- and post-operative hypoproteinemia: 50 to 75 g.<br>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 100mL.<br>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)
- This product is made from human plasma and may contain infectious agents, e.g., viruses and, theoretically, the Creutzfeldt-Jakob disease agent. (5.7)

----- **ADVERSE REACTIONS** -----

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

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

----- **USE IN SPECIFIC POPULATIONS** -----

- Pregnancy: No human or animal data. Use only if clearly needed. (8.1)

See 17 for **PATIENT COUNSELING INFORMATION**.

Revised: 7/2016

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

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**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.<sup>1,2,3</sup>

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

ALBUTEIN 5% may be of value in the treatment of shock or hypotension in renal dialysis patients.<sup>1</sup>

## 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.<sup>4,5,6</sup>

## 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.<sup>7,8,9</sup> Septic patients and patients undergoing major surgery may lose more than half of their circulating plasma volume.<sup>1,10</sup> Treatment with ALBUTEIN 5% may be of value in such cases, especially when plasma colloid oncotic pressure is abnormally low.<sup>1</sup>

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.<sup>2,11,12</sup> Protein loss from the third space due to infection (acute peritonitis, pancreatitis, mediastinitis or extensive cellulitis) may require treatment with an infusion of albumin.<sup>13,14</sup>

## 1.4 Plasma Exchange

ALBUTEIN 5% may be used as a replacement fluid during therapeutic Plasma Exchange treatments.<sup>15</sup>

# 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.<br>If hemodynamic stability is not achieved within 15 to 30 minutes, an additional dose may be given.<br>Hemodilution may follow administration of ALBUTEIN 5%.<br>Anemia resulting from hemorrhage should be corrected by administration of compatible red blood cells or compatible whole blood.<br>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<br>For pre- and post-operative hypoproteinemia: 50 to 75 g.<br>In burns, therapy usually starts with administration of large volumes of crystalloid solution to maintain plasma volume.<br>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.<br>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

- ALBUTEIN 5% is a clear and slightly viscous solution. Visually inspect parenteral drug products for particulate matter and discoloration prior to administration, whenever solution and container permit. Do not use if the solution is turbid or if there is sediment in the bottle.
- Do not freeze.
- Warm product to room temperature before use if large volumes are administered.
- ALBUTEIN 5% contains no preservatives. Do not begin administration more than 4 hours after the container has been entered. Discard unused portion.
- Do not dilute with sterile water for injection [see *Warnings and Precautions* (5.6)].
- Adjust the infusion rate to the individual circumstances and the indication. In plasma exchange, adjust the infusion rate to the rate of plasma removal.

## 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. A theoretical risk for transmission of Creutzfeldt-Jakob disease (CJD) is also considered extremely remote. No cases of transmission of viral diseases or CJD have 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 Post-marketing 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**

Pregnancy Category C. Animal reproduction studies have not been conducted with ALBUTEIN 5%. It is also not known whether ALBUTEIN 5% can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. ALBUTEIN 5% should be given to a pregnant woman only if clearly needed.

### **8.2 Labor and Delivery**

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

### **8.3 Nursing Mothers**

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

### **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 isotonicly 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 against the possibility of transmitting 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 isoosmotic 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**

1. Tullis JL. Albumin: 1. Background and Use. 2. Guidelines for Clinical Use. *JAMA*. 1977; 237:355-360, 460-463.
2. Vermeulen LC, et al. A Paradigm for Consensus. *Arch Intern Med*. 1995;155:373-379.
3. SAFE Study investigators. A comparison of albumin and saline for fluid resuscitation in the intensive care unit. *N Engl J Med*. 2004;350:2247-2256.
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5. Russell JA, Navickis RJ, Wilkes MM. Albumin versus crystalloid for pump priming in cardiac surgery: meta-analysis of controlled trials. *J Cardiothorac Vasc Anesth*. 2004;18:429-37.
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15. Szczepiorkowski ZM, Bandarenko N, Kim HC, et al. Guidelines on the use of therapeutic apheresis in clinical practice-evidence-based approach from the Apheresis applications committee of the American Society for Apheresis. *J Clin Apheresis.* 2007;22:106-175.

## 16 HOW SUPPLIED/STORAGE AND HANDLING

ALBUTEIN 5% is supplied in single-use, individually laser etched vials.

The following vial sizes of ALBUTEIN 5% are available:

| <u>NDC Number</u> | <u>Fill Size</u> | <u>Grams Protein</u> |
|-------------------|------------------|----------------------|
| 68516-5214-5      | 50 mL            | 2.5 g                |
| 68516-5214-1      | 250 mL           | 12.5 g               |
| 68516-5214-2      | 500 mL           | 25.0 g               |

Each vial size label incorporates integrated hangers. Each label has a peel-off strip showing the product name and lot number.

ALBUTEIN 5% is stable for three years provided the storage temperature does not exceed 30 °C. Protect from freezing.

## 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 inactivation and/or removal of certain viruses during the manufacturing process [see *Warnings and Precautions* (5.7)].

Manufactured by:

**Grifols Biologicals Inc.**



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

3043519

Principal Display Panel – 50 mL Vial Label

GRIFOLS

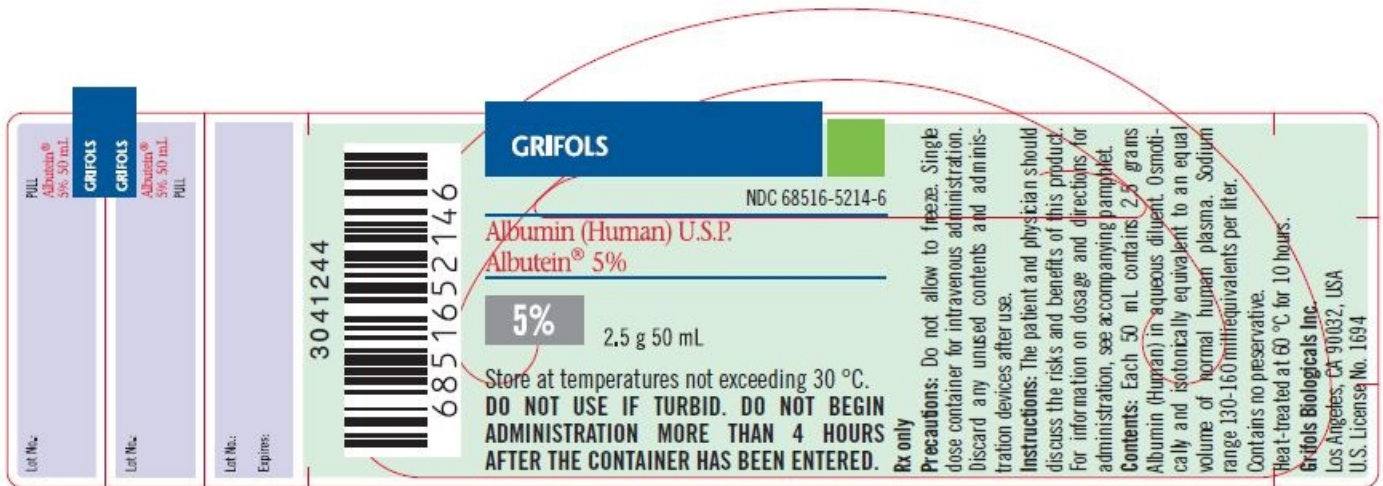
NDC 68516-5214-6

Albumin (Human) U.S.P.  
Albutein<sup>®</sup> 5%

5% 2.5 g 50 mL

Store at temperatures not exceeding 30° C.

**DO NOT USE IF TURBID. DO NOT BEGIN ADMINISTRATION MORE THAN 4 HOURS AFTER THE CONTAINER HAS BEEN ENTERED.**



Principal Display Panel – 50 mL Carton Label

GRIFOLS

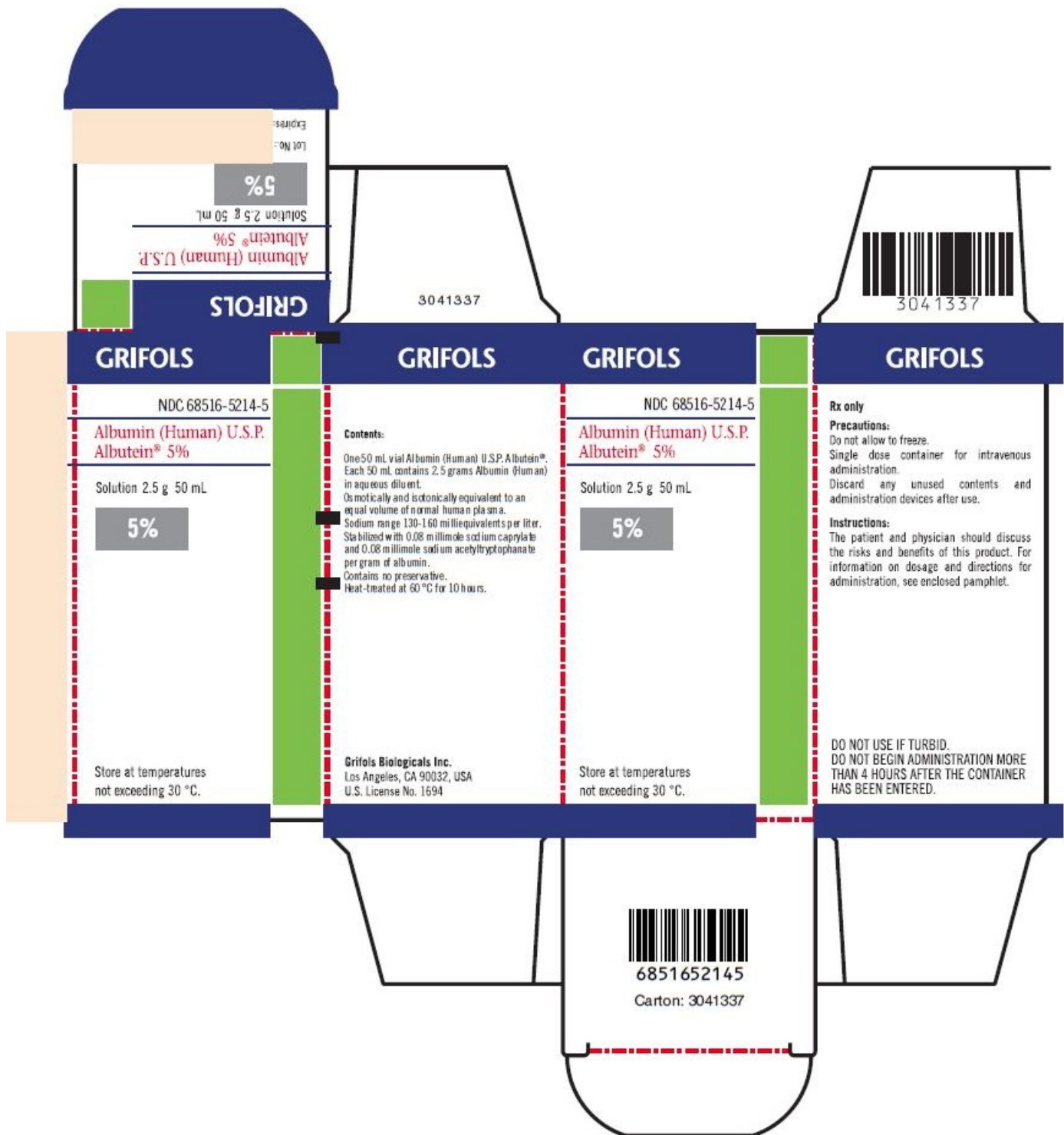
NDC 68516-5214-5

Albumin (Human) U.S.P.  
Albutein<sup>®</sup> 5%

Solution 2.5 g 50 mL

5%

Store at temperatures not exceeding 30 °C.



Principal Display Panel – 250 mL Vial Label

GRIFOLS

NDC 68516-5214-3

Albumin (Human) U.S.P.  
Albutein® 5%

5% 12.5 g 250 mL

Store at temperatures not exceeding 30° C.

**DO NOT USE IF TURBID. DO NOT BEGIN ADMINISTRATION MORE**

**THAN 4 HOURS AFTER THE CONTAINER HAS BEEN ENTERED.**

Lot No.:  
Lot No.:  
Lot No. Expires:

3043014

**GRIFOLS**

NDC 68516-5214-3

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

**5%** 12.5 g 250 mL

Store at temperatures not exceeding 30 °C.  
**DO NOT USE IF TURBID. DO NOT BEGIN ADMINISTRATION MORE  
THAN 4 HOURS AFTER THE CONTAINER HAS BEEN ENTERED.**

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

**Rx only**

**Precautions:** Do not allow to freeze. Single dose container for intravenous administration. Discard any unused contents and administration devices after use.

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

**Contents:** Each 250 mL contains 12.5 grams Albumin (Human) in aqueous diluent. Osmotically and isotonicity equivalent to an equal volume of normal human plasma. Sodium range 130–160 milliequivalents per liter.

Contains no preservative.  
Heat-treated at 60 °C for 10 hours.

**Grifols Biologicals Inc.**  
Los Angeles, CA 90032, USA  
U.S. License No. 1639

6851652143

Principal Display Panel – 250 mL Carton Label

GRIFOLS

NDC 68516-5214-1

Albumin (Human) U.S.P.  
Albutein® 5%

Solution 12.5 g 250 mL

5%

Store at temperatures not exceeding 30° C.



Principal Display Panel – 500 mL Vial Label

GRIFOLS

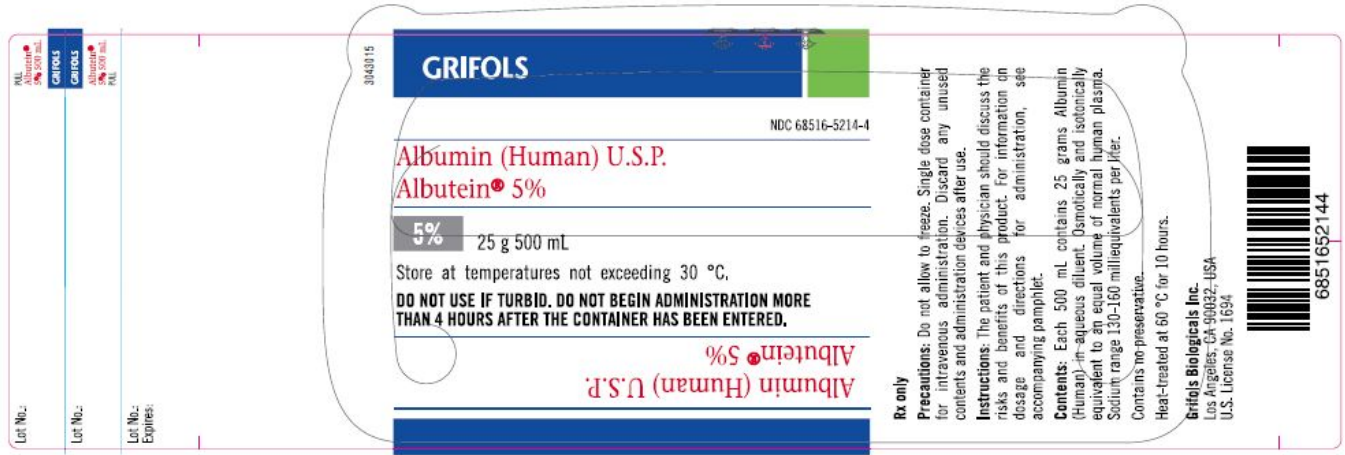
NDC 68516-5214-4

Albumin (Human) U.S.P.  
Albutein® 5%

5% 25 g 500 mL

Store at temperatures not exceeding 30° C.

**DO NOT USE IF TURBID. DO NOT BEGIN ADMINISTRATION MORE THAN 4 HOURS AFTER THE CONTAINER HAS BEEN ENTERED.**



Principal Display Panel – 500 mL Carton Label

GRIFOLS

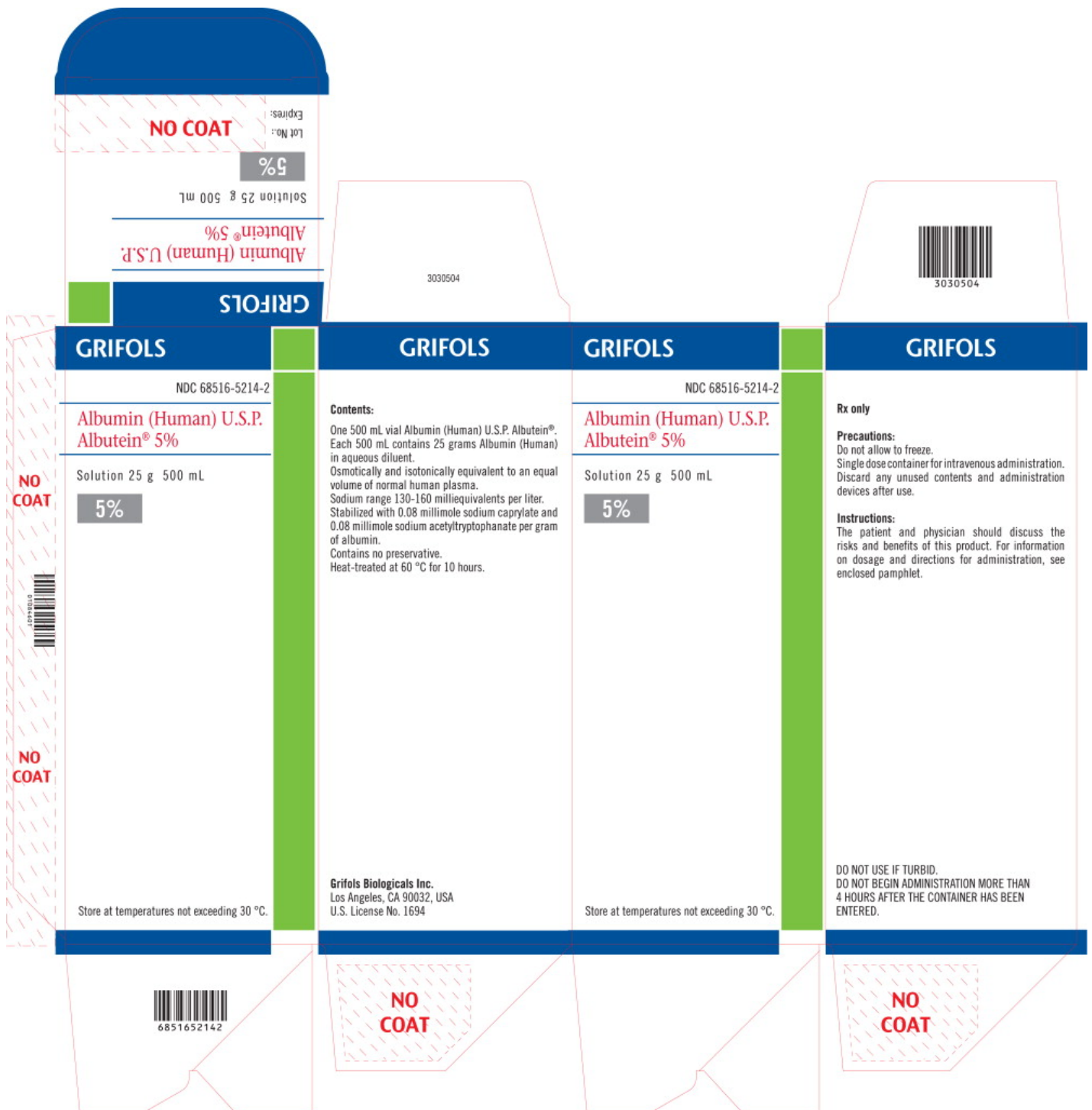
NDC 68516-5214-2

Albumin (Human) U.S.P.  
Albutein® 5%

Solution 25 g 500 mL

5%

Store at temperatures not exceeding 30° C.



## ALBUTEIN

albumin (human) injection, solution

### Product Information

|                                |                   |                           |                |
|--------------------------------|-------------------|---------------------------|----------------|
| <b>Product Type</b>            | PLASMA DERIVATIVE | <b>Item Code (Source)</b> | NDC:68516-5214 |
| <b>Route of Administration</b> | INTRAVENOUS       |                           |                |

### Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-----------------|-------------------|----------|
|-----------------|-------------------|----------|

|   |   |   |                             |                           |
|---|---|---|-----------------------------|---------------------------|
| <b>Albumin Human</b> (UNII: ZIF514RVZR) (Albumin Human - UNII:ZIF514RVZR) |   | Albumin Human                                       | 12.5 g in 250 mL            |                           |
| <b>Inactive Ingredients</b>   |   |   |                             |                           |
| <b>Ingredient Name</b>  |   |   | <b>Strength</b>             |                           |
| Sodium Chloride (UNII: 451W47IQ8X)  |   |   |                             |                           |
| Sodium Caprylate (UNII: 9XTM81VK2B)                                       |   |   |                             |                           |
| Sodium Acetyltryptophanate (UNII: 3EN9H0M2FX)                             |   |   |                             |                           |
| Water (UNII: 059QF0K00R)  |   |   |                             |                           |
| <b>Packaging</b>  |   |   |                             |                           |
| <b>#</b>  | <b>Item Code</b>                                | <b>Package Description</b>                          | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
| 1   | NDC:68516-5214-1                                | 1 in 1 CARTON                                       |                             |                           |
| 1   | NDC:68516-5214-3                                | 250 mL in 1 VIAL; Type 0: Not a Combination Product |                             |                           |
| 2   | NDC:68516-5214-2                                | 1 in 1 CARTON                                       |                             |                           |
| 2   | NDC:68516-5214-4                                | 500 mL in 1 VIAL; Type 0: Not a Combination Product |                             |                           |
| 3   | NDC:68516-5214-5                                | 1 in 1 CARTON                                       |                             |                           |
| 3   | NDC:68516-5214-6                                | 50 mL in 1 VIAL; Type 0: Not a Combination Product  |                             |                           |
| <b>Marketing Information</b>  |   |   |                             |                           |
| <b>Marketing Category</b>   | <b>Application Number or Monograph Citation</b> | <b>Marketing Start Date</b>                         | <b>Marketing End Date</b>   |                           |
| BLA   | BLA102478                                       | 08/15/1978  |                             |                           |

**Labeler** - GRIFOLS USA, LLC (048987452)

### Establishment

| Name                     | Address | ID/FEI    | Business Operations     |
|--------------------------|---------|-----------|-------------------------|
| Grifols Biologicals Inc. |         | 092694538 | manufacture(68516-5214) |

### Establishment

| Name                     | Address | ID/FEI    | Business Operations     |
|--------------------------|---------|-----------|-------------------------|
| Grifols Biologicals Inc. |         | 121076871 | manufacture(68516-5214) |

### Establishment

| Name                      | Address | ID/FEI    | Business Operations     |
|---------------------------|---------|-----------|-------------------------|
| Grifols Therapeutics Inc. |         | 611019113 | manufacture(68516-5214) |

### Establishment

| Name                 | Address | ID/FEI    | Business Operations     |
|----------------------|---------|-----------|-------------------------|
| INSTITUTO GRIFOLS SA |         | 465562213 | manufacture(68516-5214) |