# HUMAN ALBUMIN GRIFOLS - albumin (human) solution
# GRIFOLS USA, LLC

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**HIGHLIGHTS OF PRESCRIBING INFORMATION**
**These highlights do not include all the information needed to use Human Albumin Grifols 25% safely and effectively. See full prescribing information for Human Albumin Grifols 25%.**
**Human Albumin Grifols 25%**
**Albumin (Human) U.S.P.**
**25% solution**
**Initial U.S. Approval: 2003**

**RECENT MAJOR CHANGES**

**Indications and Usage**, Ovarian hyperstimulation syndrome (1.5), Adult Respiratory Distress Syndrome (1.7), Prevention of Central Volume Depletion after Paracentesis Due to Cirrhotic Ascites (1.8) 04/2012
**Dosage and Administration**, Hypovolemia, Cardiopulmonary Bypass, Acute Nephrosis, Hypoalbuminemia, Ovarian Hyperstimulation Syndrome, Neonatal Hyperbilirubinemia, Adult Respiratory Distress Syndrome, Prevention of Central Volume Depletion after Paracentesis due to Cirrhotic Ascites (2.1) 04/2012
**Warnings and Precautions**, Hypersensitivity (5.1), Hypervolemia/Hemodilution (5.2), Dehydration (5.3), Electrolyte Imbalance (5.4), Coagulation Abnormalities (5.5), Laboratory Monitoring (5.6), Application Precautions (5.7) 04/2012

**INDICATIONS AND USAGE**

Human Albumin Grifols 25% is an albumin solution indicated for:

- Hypovolemia. (1.1)
- Cardiopulmonary bypass procedures. (1.2)
- Acute nephrosis. (1.3)
- Hypoalbuminemia. (1.4)
- Ovarian hyperstimulation syndrome. (1.5)
- Neonatal hyperbilirubinemia. (1.6)
- Adult respiratory distress syndrome (ARDS). (1.7)
- Prevention of central volume depletion after paracentesis due to cirrhotic ascites. (1.8)

**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 25 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) |
| Acute nephrosis | Adults: 25 g together with diuretic once a day for 7 - 10 days (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<br>dose of 25 g and dose adjustment to maintain plasma protein concentration of 2.5 g per 100 mL.<br>Third space protein loss due to infection: initial dose of 50 to 100 g (2.1) |
| Ovarian hyperstimulation syndrome | Adults: 50 g to 100 g over 4 hours and repeated at 4 - 12 hour intervals as necessary (2.1) |
| Neonatal hyperbilirubinemia | 1 g per kilogram body weight prior to or during exchange transfusion (2.1) |
| Adult respiratory distress syndrome (ARDS) | Adults: 25 g over 30 minutes and repeated at 8 hours for 3 days, if necessary (2.1) |
| Prevention of central volume depletion after paracentesis due to cirrhotic ascites | Adults: 8 g for every 1000 mL of ascitic fluid removed (2.1) |

Do not dilute with sterile water for injection as this may cause hemolysis in recipients. (5.7)

**DOSAGE FORMS AND STRENGTHS**

Human Albumin Grifols 25% is a solution containing 250 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)
- When concentrated albumin is administered, care must be taken to assure adequate hydration of the patient. (5.3)
- Monitor electrolytes, coagulation and hematology parameters, and hemodynamic status when albumin is administered. (5.4, 5.5, 5.6)
- Do not dilute with sterile water for injection. (5.7)
- This product is made from human plasma and may contain infectious agents, e.g., viruses and, theoretically, the Creutzfeldt-Jakob disease agent. (5.8)

**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**.

**USE IN SPECIFIC POPULATIONS**

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

**See 17 for PATIENT COUNSELING INFORMATION.**

**Revised: 4/2012**

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## FULL PRESCRIBING INFORMATION: CONTENTS*

* 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.[1,2,3]

Acute liver failure is a special situation in which both hypovolemia and hypoalbuminemia can be present. Human Albumin Grifols® 25% can be used in such cases.[1]

Human Albumin Grifols 25% 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 Acute Nephrosis (Treatment Adjunct)

Human Albumin Grifols 25% may be used to treat peripheral edema in patients with acute nephrosis who are refractory to cyclophosphamide, corticosteroid therapy or diuretics.[1,2,7]

### 1.4 Hypoalbuminemia

Human Albumin Grifols 25% 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 Human Albumin Grifols 25% administration will be temporary unless the underlying disorder is reversed.[8,9,10]

Septic patients and patients undergoing major surgery may lose more than half of their circulating plasma volume.[1,11] Treatment with Human Albumin Grifols 25% may be of value in such cases,

especially when plasma colloid oncotic pressure is abnormally low.[1] In first 24 hours after thermal injury, large volumes of crystalloids are infused to restore the depleted extracellular fluid volume. Beyond 24 hours, Human Albumin Grifols 25% can be used to maintain plasma colloid osmotic pressure.[2,12,13]

Protein loss from the third space due to infection (acute peritonitis, pancreatitis, mediastinitis or extensive cellulitis) may require treatment with an infusion of albumin.[14,15]

### 1.5 Ovarian Hyperstimulation Syndrome

Human Albumin Grifols 25% may be used as a plasma volume expander in fluid management relating to severe forms of ovarian hyperstimulation syndrome.[16,17]

### 1.6 Neonatal Hyperbilirubinemia

Human Albumin Grifols 25% is indicated for the treatment of neonatal hyperbilirubinemia. It may be used prior to or during an exchange procedure in an attempt to bind free bilirubin and enhance its excretion.[18,19,20]

### 1.7 Adult Respiratory Distress Syndrome (ARDS) (Treatment Adjunct)

Human Albumin Grifols 25% infusions may be indicated in conjunction with diuretics to correct fluid overload and hypoproteinemia associated with ARDS.[6,21]

### 1.8 Prevention of Central Volume Depletion after Paracentesis due to Cirrhotic Ascites (Treatment Adjunct)

Human Albumin Grifols 25% may be used to maintain cardiovascular function following removal of large volumes of ascitic fluid after paracentesis due to cirrhotic ascites.[2,22,23,24]

## 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 25 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 Human Albumin Grifols 25%.<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 min is usually indicated.<br>For renal dialysis, the initial dose should not exceed 25 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. |
| Acute nephrosis | Adults: 25 g together with diuretic once a day for 7 - 10 days. |
| 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. 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. |
| Ovarian hyperstimulation syndrome | Adults: 50 g to 100 g over 4 hours and repeated at 4-12 hour intervals as necessary, when infusion of normal saline fails to achieve or maintain hemodynamic stability and urine output. |
| Neonatal hyperbilirubinemia | 1 g per kilogram body weight prior to or during exchange transfusion. |
| Adult respiratory distress syndrome (ARDS) | Adults: 25 g over 30 minutes and repeated at 8 hours for 3 days, if necessary. |
| Prevention of central volume depletion after paracentesis due to cirrhotic ascites | Adults: 8 g for every 1000 mL of ascitic fluid removed. |

### 2.2 Administration

Intravenous use only

- Human Albumin Grifols 25% 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.
- Human Albumin Grifols 25% 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 injections. The product can be diluted in an isotonic solution (e.g., 5% Dextrose in Water or 0.9% sodium chloride) [see *Warnings and Precautions* (5.7)].
- Adjust the infusion rate to the individual circumstances and the indication.

## 3 DOSAGE FORMS AND STRENGTHS

Human Albumin Grifols 25% is a solution containing 250 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 cardiovascular 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 Dehydration

The colloid-osmotic effect of human albumin 25% is approximately five times that of blood plasma. 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. Patients with marked dehydration require administration of additional fluids.

### 5.4 Electrolyte Imbalance

20% - 25% human albumin solutions are relatively low in electrolytes compared to 4% - 5% human albumin solutions. Monitor regularly the electrolyte status of the patient and take appropriate steps to restore or maintain the electrolyte balance when albumin is administered.

### 5.5 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).

### 5.6 Laboratory Monitoring

Monitor regularly hemodynamic parameters during administration of Human Albumin Grifols 25%; this may include:

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

### 5.7 Application Precautions

Human Albumin Grifols 25% must not be diluted with sterile water for injection as this may cause hemolysis in recipients. The product can be diluted in an isotonic solution (e.g., 5% Dextrose in Water or 0.9% sodium chloride) [see *Dosage and Administration* (2.2)].

### 5.8 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 ever been identified for Human Albumin Grifols 25%.

## 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 Human Albumin Grifols 25% 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 Human Albumin Grifols 25%.

### 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 Human Albumin Grifols (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

Human Albumin Grifols 25% 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 Human Albumin Grifols 25%. It is also not known whether Human Albumin Grifols 25% can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Human Albumin Grifols 25% 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

Human Albumin Grifols 25% is a sterile aqueous solution for single dose intravenous administration containing 25% human albumin (weight/volume). Human Albumin Grifols 25% 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. The colloid osmotic effect of human albumin 25% is approximately five times that of normal human plasma.

A liter of Human Albumin Grifols 25% solution contains 130-160 milliequivalents of sodium ion. The aluminium content of the solution is not more than 200 micrograms per liter during the shelf life of the product.

The product contains no preservatives. Human Albumin Grifols 25% is manufactured from Source Plasma collected from FDA approved plasmapheresis centers in the United States. Human Albumin Grifols 25% 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 25% has a corresponding hyperoncotic effect.

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 the 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

Human Albumin Grifols 25% is supplied in single-use, individually laser etched vials.

The following vial sizes of Human Albumin Grifols 25% are available:

| NDC Number | Fill Size | Grams Protein |
|---|---|---|
| 61953-0002-1 | 50 mL | 12.5 g |
| 61953-0002-2 | 100 mL | 25 g |

Each vial has an integral suspension band and a label with a peel-off strip showing the product name and lot number.

Human Albumin Grifols 25% 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 Human Albumin Grifols 25% 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 Human Albumin Grifols 25% 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 Human Albumin Grifols 25% 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* (5.8)].

Manufactured by:
**Instituto Grifols, S.A.**
Barcelona, Spain.
U.S. License No. 1181

3054988

**Principal Display Panel – 50 mL Vial**

NDC 61953-0002-3

**Albumin (Human) U.S.P. Human Albumin Grifols® 25%**

12.5 g 50 mL Rx only.
Dosage and directions for administration, see package insert.
Store at temperatures not exceeding 30 °C
DO NOT USE IF TURBID. DO NOT BEGIN ADMINISTRATION MORE THAN 4 HOURS AFTER CONTAINER HAS BEEN ENTERED.

Manufactured by **Instituto Grifols, S.A.** Barcelona – SPAIN.
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TO HANG PULL HERE

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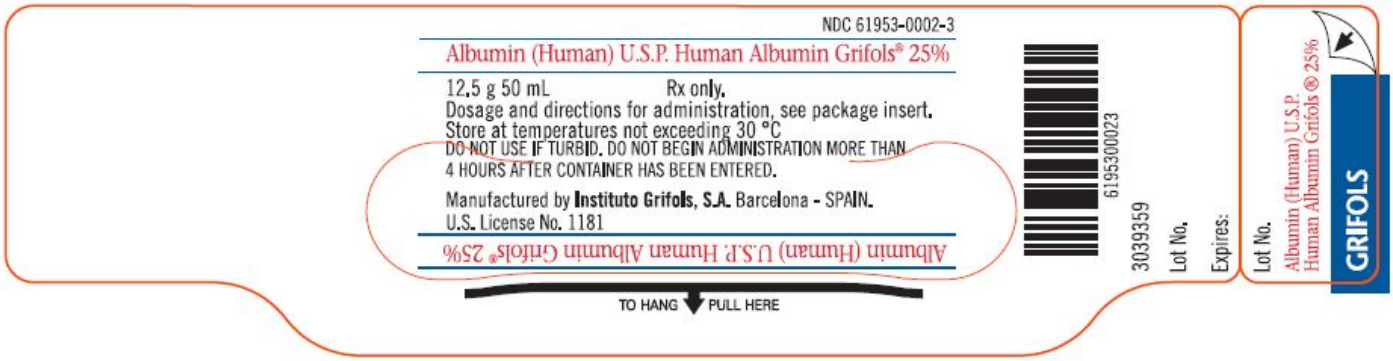
Lot No.

Expires:




**Principal Display Panel – 50 mL Carton**

GRIFOLS

NDC 61953-0002-1

**Albumin (Human) U.S.P. Human Albumin Grifols®**
25% Solution

12.5 g 50 mL

DO NOT USE IF TURBID.

DO NOT BEGIN ADMINISTRATION MORE THAN 4 HOURS AFTER THE CONTAINER HAS BEEN ENTERED.

CONTENTS

One each: 50 mL vial Albumin (Human) U.S.P. HUMAN ALBUMIN GRIFOLS® 25%

Each 50 mL contains 12.5 grams Albumin (Human) in aqueous diluent. Osmotically equivalent to 250 mL of plasma. Sodium range 130-160 milliequivalents per liter.

Stabilized with 0.08 millimole sodium caprylate and 0.08 millimole sodium acetyltryptophanate per gram of protein.

Contains no preservatives.

Heat-treated at 60 °C for 10 hours.

The patient and physician should discuss the risks and benefits of this product.

STORE AT TEMPERATURES NOT EXCEEDING 30°C.

Rx only.

PRECAUTION

Do not allow to freeze.

Single dose container for intravenous administration.

Discard any unused contents and administration devices after use.

In case of dehydration, administer additional fluids with or immediately following HUMAN ALBUMIN GRIFOLS® 25%

INSTRUCTIONS

For information on dosage and directions for administration, see enclosed package insert.

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**Instituto Grifols, S.A.**
Barcelona - SPAIN
U.S. Licence No. 1181

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Lot: XXXXXXXXXX
Exp.: DD-MMM-YY

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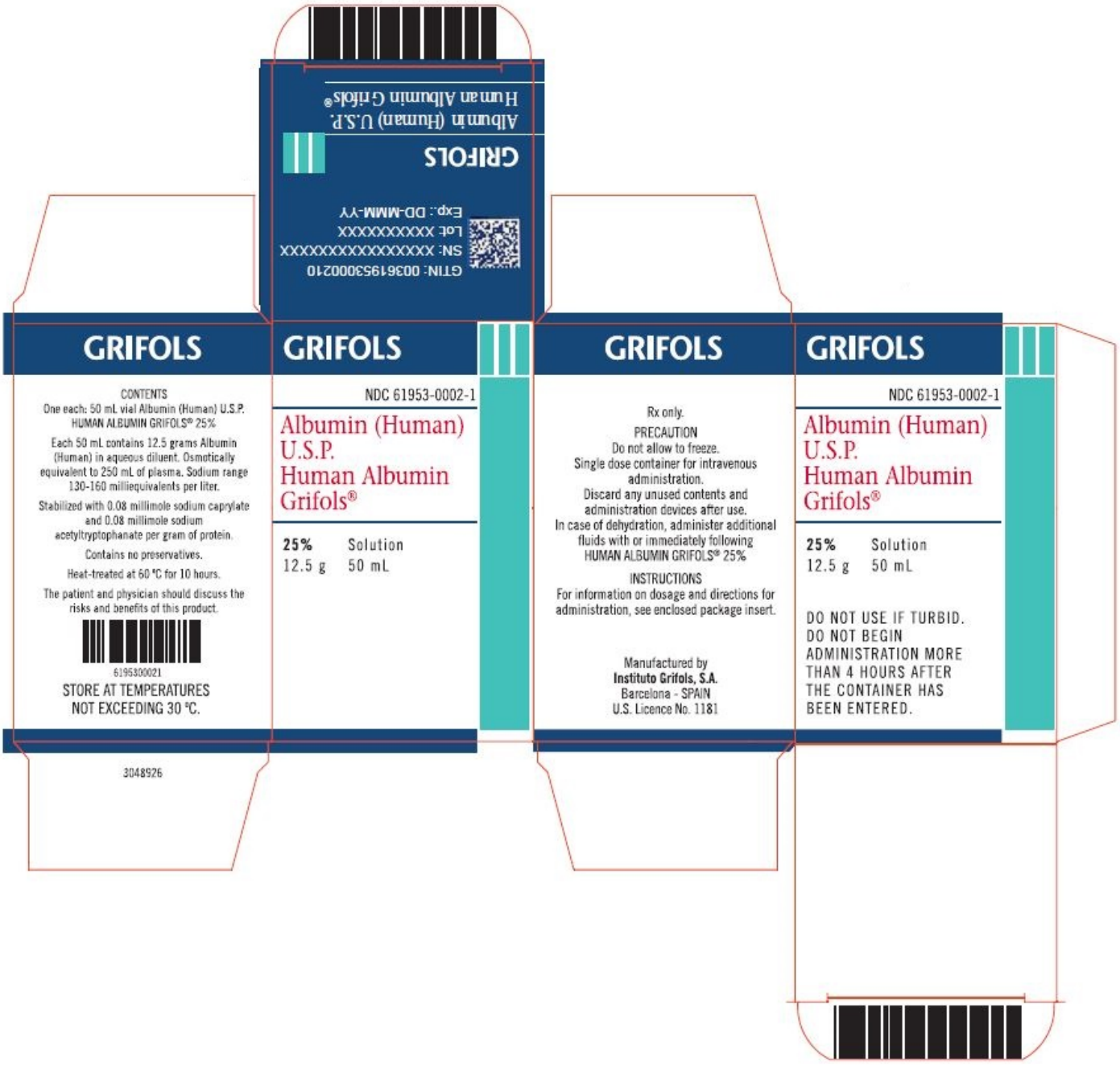


**Principal Display Panel – 100 mL Vial**

GRIFOLS

NDC 61953-0002-4

**Albumin (Human) U.S.P. Human Albumin Grifols® 25% 100 mL**

25 g 100 mL Rx only.

CONTENTS: Each 100 mL contains 25 grams Albumin (Human) in aqueous diluent.
Osmotically equivalent to 500 mL of plasma. Sodium range 130-160 milliequivalents per liter.
Dosage and directions for administration, see package insert.
Contains no preservatives. Store at temperatures not exceeding 30 °C

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

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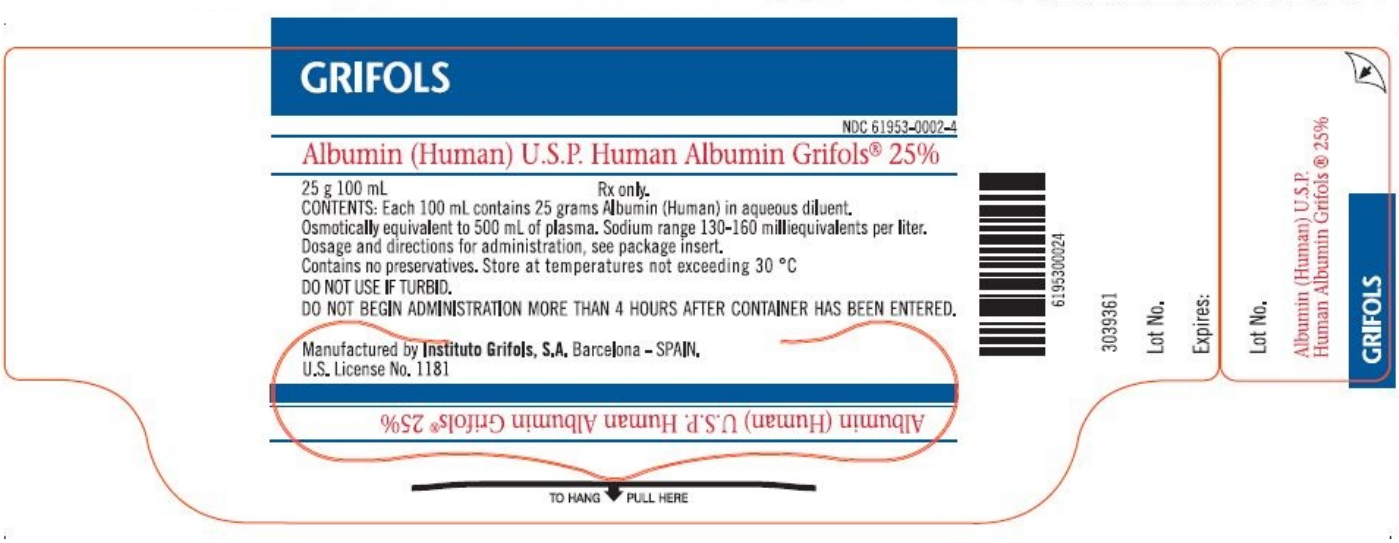
Lot No.

Expires:




**Principal Display Panel – 100 mL Carton**

GRIFOLS

NDC 61953-0002-2

**Albumin (Human) U.S.P. Human Albumin Grifols®**

25% Solution
25 g 100 mL

DO NOT USE IF TURBID.

DO NOT BEGIN ADMINISTRATION MORE THAN 4 HOURS AFTER THE CONTAINER HAS BEEN ENTERED.

CONTENTS

One each: 100 mL vial Albumin (Human) U.S.P. HUMAN ALBUMIN GRIFOLS® 25%

Each 100 mL contains 25 grams Albumin (Human) in aqueous diluent. Osmotically equivalent to 500 mL

of plasma. Sodium range 130-160 milliequivalents per liter.

Stabilized with 0.08 millimole sodium caprylate and 0.08 millimole sodium acetyltryptophanate per gram of protein.

Contains no preservatives.

Heat-treated at 60 °C for 10 hours.

The patient and physician should discuss the risks and benefits of this product.

STORE AT TEMPERATURES NOT EXCEEDING 30°C.

Rx only.

PRECAUTION

Do not allow to freeze.

Single dose container for intravenous administration.

Discard any unused contents and administration devices after use.

In case of dehydration, administer additional fluids with or immediately following HUMAN ALBUMIN GRIFOLS® 25%

INSTRUCTIONS

For information on dosage and directions for administration, see enclosed package insert.

Manufactured by
**Instituto Grifols, S.A.**
Barcelona - SPAIN
U.S. Licence No. 1181

GTIN: 00361953000227
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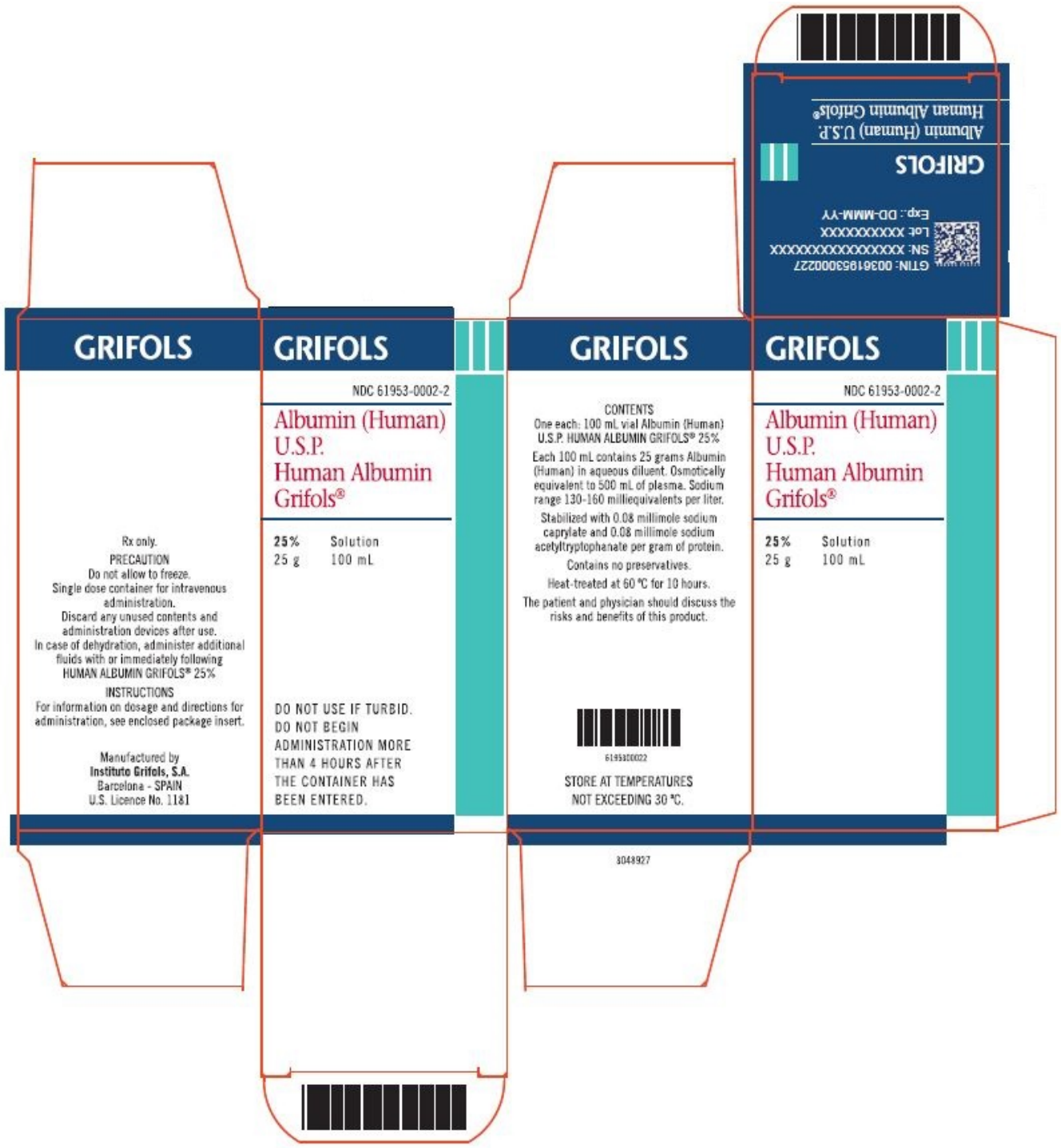


# HUMAN ALBUMIN GRIFOLS

albumin (human) solution

| Product Information | | | |
|---|---|---|---|
| **Product Type** | PLASMA DERIVATIVE | **Item Code (Source)** | NDC:61953-0002 |
| **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 50 mL |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **Sodium Caprylate** (UNII: 9XTM81VK2B) | |
| **Sodium Acetyltryptophanate** (UNII: 3EN9H0M2FX) | |
| **Water** (UNII: 059QF0KO0R) | |
| **Sodium Chloride** (UNII: 451W47IQ8X) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:61953-0002-1 | 1 in 1 CARTON | | |
| **1** | NDC:61953-0002-3 | 50 mL in 1 VIAL; Type 0: Not a Combination Product | | |
| **2** | NDC:61953-0002-2 | 1 in 1 CARTON | | |
| **2** | NDC:61953-0002-4 | 100 mL in 1 VIAL; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| BLA | BLA103352 | 06/11/2003 | |

## Labeler - GRIFOLS USA, LLC (048987452)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Instituto Grifols, S.A. | | 465562213 | manufacture(61953-0002) |

Revised: 12/2019 GRIFOLS USA, LLC