

# GRIFOLS

## Grifols introduces ALBUTEIN FlexBag™ (Albumin [Human] U.S.P.) in 5% and 25% concentrations, a more convenient option for healthcare professionals

- *The ALBUTEIN FlexBag, now available in the U.S., comes in several sizes: 250 mL and 500 mL bags for 5%, and 50 mL and 100 mL bags for 25%*
- *Grifols is the only manufacturer to offer a 500 mL 5% albumin option for customers in an easy-to-use, flexible container*
- *It is provided in an environmentally friendly bag, free of plasticizers, offering healthcare professionals a more sustainable choice*

**Barcelona, Spain, November 4, 2021** – Grifols (MCE: GRF, MCE: GRF.P, and NASDAQ: GRFS), a leading global producer of plasma-derived medicines, today announced the launch of its latest albumin portfolio innovation, ALBUTEIN FlexBag™ (Albumin [Human] U.S.P.) in 5% and 25% concentrations.

Meeting the needs of hospitals and pharmacies across the U.S., the ALBUTEIN FlexBag features a port that is easy-to-use, allowing the minimization of bubble accumulation during infusion, and easy-to-spike, helping nurse and hospital teams avoid needle sticks. The FlexBag also features a flexible container that allows for simple storage and greater convenience, with no requirements for vented infusion sets or filters.

“Grifols’ first 5% and 25% FlexBag is another example of the company’s continued dedication to innovation and listening to customers’ needs,” said Bill Zabel, President, Grifols North America Sales and Commercial Operations. “This step forward will expand and differentiate Grifols’ industry-leading albumin portfolio to benefit patients and bring convenient, flexible container options to our customers.”

ALBUTEIN FlexBag 5% and 25% each come in two sizes. The 5% concentration, approved by the U.S. Food and Drug Administration (FDA) in July 2021, features 250 mL and 500 mL bags. Earlier in the year the FDA approved 25% concentration, which features 50 mL and 100 mL bags.

Sustainability was key for Grifols when developing the environmentally friendly ALBUTEIN FlexBag. Both the ALBUTEIN FlexBag flexible container and protective overwrap are latex-free and do not contain polyvinyl chloride (PVC), diethylhexyl phthalate (DEHP), or other plasticizers. In fact, in a study comparing the manufacturing process of ALBUTEIN FlexBag and ALBUTEIN vials, the FlexBag manufacturing life cycle resulted in a 40% reduction in carbon footprint,<sup>1</sup> creating a more sustainable option for hospitals and pharmacies.

The launch of ALBUTEIN FlexBag solidifies Grifols commitment to R+D+i, which has enabled the company to further expand its industry-leading portfolio of plasma-derived medicines for patients and healthcare professionals. It is now available to U.S. healthcare professionals through a broad

---

<sup>1</sup> Grifols data on file.

# GRIFOLS

distribution network.

**Please see Important Safety Information for ALBUTEIN FlexBag 5% below and click to access the full [Prescribing Information](#).**

**Please see Important Safety Information for ALBUTEIN FlexBag 25% below and click to access the full [Prescribing Information](#).**

For more information, visit our [website](#). For Grifols USA Customer Service during regular business hours, 8:30 AM – 5:00 PM Eastern Standard Time, call 1-800-243-4153 and 1-888-325-8579, option 3, during the hours of 5:00 PM – 8:00 PM Eastern Standard Time.

---

## IMPORTANT SAFETY INFORMATION

ALBUTEIN® 25% (albumin [human] U.S.P.) is indicated for: hypovolemia, cardiopulmonary bypass procedures, acute nephrosis, hypoalbuminemia, ovarian hyperstimulation syndrome, neonatal hyperbilirubinemia, adult respiratory distress syndrome (ARDS), and prevention of central volume depletion after paracentesis due to cirrhotic ascites.

ALBUTEIN® 5% (albumin [human] U.S.P.) is indicated for: hypovolemia, cardiopulmonary bypass procedures, hypoalbuminemia, and plasma exchange.

ALBUTEIN 5% and 25% are contraindicated in patients with a history of hypersensitivity to albumin preparations or to any of the excipients, and in patients with severe anemia or cardiac failure with normal or increased intravascular volume.

Allergic or anaphylactic reactions require immediate discontinuation of the infusion and implementation of appropriate medical treatment.

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, 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.

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.

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

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).

Regularly monitor hemodynamic parameters during administration of ALBUTEIN® 5% and 25% (albumin [human] U.S.P.).

ALBUTEIN 5% and 25% must not be diluted with sterile water for injection as this may cause hemolysis in recipients.

# GRIFOLS

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 ALBUTEIN 5% or 25%.

The most serious adverse reactions with use of albumin are anaphylactic shock, heart failure and pulmonary edema. The most common adverse reactions are anaphylactoid type reactions. Adverse reactions to ALBUTEIN normally resolve when the infusion rate is slowed or the infusion is stopped. In case of severe reactions, the infusion should be stopped and appropriate treatment initiated.

**Please see accompanying full Prescribing Information for [ALBUTEIN FlexBag™ 5%](#) and [ALBUTEIN FlexBag™ 25%](#).**

**You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.**

---

## About Grifols

Grifols is a global healthcare company founded in Barcelona in 1909 committed to improving the health and well-being of people around the world. Its four divisions – Bioscience, Diagnostic, Hospital and Bio Supplies – develop, produce and market innovative solutions and services that are sold in more than 100 countries.

Pioneers in the plasma industry, Grifols operates a growing network of donation centers worldwide. It transforms collected plasma into essential medicines to treat chronic, rare and, at times, life-threatening conditions. As a recognized leader in transfusion medicine, Grifols also offers a comprehensive portfolio of solutions designed to enhance safety from donation to transfusion. In addition, the company supplies tools, information and services that enable hospitals, pharmacies and healthcare professionals to efficiently deliver expert medical care.

Grifols, with more than 24,000 employees in more than 30 countries and regions, is committed to a sustainable business model that sets the standard for continuous innovation, quality, safety and ethical leadership.

In 2020, Grifols' economic impact in its core countries of operation was EUR 7.5 billion. The company also generated 140,000 jobs, including indirect and induced.

The company's class A shares are listed on the Spanish Stock Exchange, where they are part of the Ibex-35 (MCE:GRF). Grifols' non-voting class B shares are listed on the Mercado Continuo (MCE:GRF.P) and on the U.S. NASDAQ through ADRs (NASDAQ:GRFS).

For more information, please visit [www.grifols.com](http://www.grifols.com)

### Media Contact:

Caleb Fernandez-Schendt  
Corporate Communications  
[caleb.fernandezschendt@grifols.com](mailto:caleb.fernandezschendt@grifols.com)  
(919) 316-2128

### Media Press Office

[media@grifols.com](mailto:media@grifols.com)  
Tel. +34 571 00 02

# GRIFOLS

## **LEGAL DISCLAIMER**

The facts and figures contained in this report that do not refer to historical data are “future projections and assumptions”. Words and expressions such as “believe”, “hope”, “anticipate”, “predict”, “expect”, “intend”, “should”, “will seek to achieve”, “it is estimated”, “future” and similar expressions, in so far as they relate to the Grifols group, are used to identify future projections and assumptions. These expressions reflect the assumptions, hypotheses, expectations and predictions of the management team at the time of writing this report, and these are subject to a number of factors that mean that the actual results may be materially different. The future results of the Grifols group could be affected by events relating to its own activities, such as a shortage of supplies of raw materials for the manufacture of its products, the appearance of competitor products on the market, or changes to the regulatory framework of the markets in which it operates, among others. At the date of compiling this report, the Grifols group has adopted the necessary measures to mitigate the potential impact of these events. Grifols, S.A. does not accept any obligation to publicly report, revise or update future projections or assumptions to adapt them to events or circumstances subsequent to the date of writing this report, except where expressly required by the applicable legislation. This document does not constitute an offer or invitation to buy or subscribe shares in accordance with the provisions of the following Spanish legislation: Royal Legislative Decree 4/2015, of 23 October, approving recast text of Securities Market Law; Royal Decree Law 5/2005, of 11 March and/or Royal Decree 1310/2005, of 4 November, and any regulations developing this legislation. In addition, this document does not constitute an offer of purchase, sale or exchange, or a request for an offer of purchase, sale or exchange of securities, or a request for any vote or approval in any other jurisdiction. The information included in this document has not been verified nor reviewed by the external auditors of the Grifols group.