**INDICATIONS AND USAGE**

FLEXBUMIN 5%, Albumin (Human) Solution is indicated for:

- Hypovolemia (1.1)
- Hypoalbuminemia: Burns (1.2)
- Cardiopulmonary Bypass Surgery (1.3)

Limitations of Use: Albumin is not indicated as an intravenous nutrient.(1.4)

**DOSAGE AND ADMINISTRATION**

For intravenous use only

- Adjust dose and rate of infusion based on the patient's clinical status. (2.1)
- Do not exceed 2 g of albumin per kg body weight for the daily dose. (2.1)
- Do not exceed 1 mL/min for patients with normal blood volume. (2.1)
- Do not dilute with Sterile Water for Injection. (2.2)

**Dosage Forms and Strengths**

FLEXBUMIN 5% is a solution containing 5 g of albumin per each 100 mL.(3)

**INDICATIONS**

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<td>Burns</td>
<td>The dosage should be determined according to the patient's condition and response to treatment after the first 24 hours.</td>
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</table>

**ADVERSE REACTIONS**

The most serious adverse reactions are hypersensitivity reaction (including anaphylactic reaction) and pulmonary edema. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Baxalta US Inc., customer service at 1-800-999-1785 or contact the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

**USE IN SPECIFIC POPULATIONS**

Pediatric Use: Ensure dose is appropriate for body weight. (8.4)

See 17 for PATIENT COUNSELING INFORMATION

Revised: 08/2019

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**FLEXBUMIN 5% Safety and Efficacy**

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

**INDICATIONS AND USAGE**

- Hypovolemia (1.1)
- Hypoalbuminemia: Burns (1.2)
- Cardiopulmonary Bypass Surgery (1.3)

**Limitations of Use**

- Albumin is not indicated as an intravenous nutrient. (1.4)

**DOSAGE AND ADMINISTRATION**

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**Dosage Forms and Strengths**

FLEXBUMIN 5% is a solution containing 5 g of albumin per each 100 mL.

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**FULL PRESCRIBING INFORMATION: CONTENTS**

1 INDICATIONS AND USAGE
   1.1 Hypovolemia
   1.2 Hypoalbuminemia
   1.3 Cardiopulmonary Bypass Surgery
   1.4 Limitations of Use
2 DOSAGE AND ADMINISTRATION
   2.1 Dose
   2.2 Administration
3 DOSAGE FORMS AND STRENGTHS
4 CONTRAINDICATIONS
5 WARNINGS AND PRECAUTIONS
   5.1 Hypersensitivity Reactions
   5.2 Hypervolemia/Hemodilution
   5.3 Hemodynamics
   5.4 Blood Pressure
   5.5 Hemolysis
   5.6 Transmission of Infectious Agents
6 ADVERSE REACTIONS
   6.1 Clinical Trials Experience
   6.2 Postmarketing Experience
8 USE IN SPECIFIC POPULATIONS
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10 OVERDOSAGE
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12 CLINICAL PHARMACOLOGY
   12.1 Mechanism of Action
   12.2 Pharmacodynamics
   12.3 Pharmacokinetics
15 REFERENCES
16 HOW SUPPLIED/STORAGE AND HANDLING
17 PATIENT COUNSELING INFORMATION

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

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**CONTRAINDICATIONS**

- History of hypersensitivity reaction to albumin preparations or to any of the excipients (N-acetyltryptophan and sodium caprylate). (4)
- Severe anemia or cardiac failure with normal or increased intravascular volume. (4)

**WARNINGS AND PRECAUTIONS**

- Hypersensitivity reactions (including anaphylactic reactions) have been observed. If hypersensitivity reaction is suspected, discontinue use and implement appropriate standard medical treatment. (5.1)
- Under conditions where hypervolemia and/or hemodilution may occur, adjust the dose and rate of infusion to the patient’s volume status. When administering large volumes, monitor hemodynamic parameters and ensure adequate substitution of other blood constituents are available (coagulation factors, platelets, and erythrocytes). Monitor electrolyte balance. (5.2)
- Closely monitor hemodynamic parameters after administration for evidence of cardiac or respiratory failure, renal failure or increasing intracranial pressure. (5.3)
- Monitor blood pressure in trauma patients and postoperative surgery patients in order to detect re-bleeding secondary to clot disruption. (5.4)
- Do not dilute with Sterile Water for Injection as this can cause hemolysis in recipients. (5.5)
- This product is made from human plasma and may contain infectious agents e.g., viruses and, theoretically, the variant Creutzfeldt-Jakob disease agent. (5.6)

**ADVERSE REACTIONS**

The most serious adverse reactions are hypersensitivity reaction (including anaphylactic reaction) and pulmonary edema. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Baxalta US Inc., customer service at 1-800-999-1785 or contact the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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**USE IN SPECIFIC POPULATIONS**

Pediatric Use: Ensure dose is appropriate for body weight. (8.4)

See 17 for PATIENT COUNSELING INFORMATION

Revised: 08/2019
FLEXBUMIN 5% [Albumin (Human)], USP, 5% Solution

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

FLEXBUMIN 5% [Albumin (Human)] is indicated for hypovolemia, hypoalbuminemia and cardiopulmonary bypass surgery.

1.1 Hypovolemia

FLEXBUMIN 5% [Albumin (Human)] is indicated for reversing hypovolemia. When hypovolemia is long standing and hypoalbuminemia exists accompanied by adequate hydration or edema, 25% albumin should be used.

1.2 Hypoalbuminemia

FLEXBUMIN 5% is indicated for patients with hypoalbuminemia resulting from one or more of the following:

1. Inadequate production (e.g., malnutrition, burns, major injury, infections)
2. Excessive catabolism (e.g., burns, major injury, pancreatitis)
3. Loss from the body (e.g., hemorrhage, excessive renal excretion, burn exudates)
4. Redistribution within the body (e.g., major surgery, various inflammatory conditions)

FLEXBUMIN 5% is indicated for patients with hypoalbuminemia accompanying severe injuries, infections or severe pancreatitis that cannot be quickly reversed and nutritional supplements fail to restore serum albumin levels.

BURNS

After the first 24 hours, FLEXBUMIN 5% is indicated in conjunction with appropriate crystalloid therapy, for the treatment of oncotic deficits following extensive burns and to replace protein loss which accompanies any severe burn.

1.3 Cardiopulmonary Bypass Surgery

Preoperative dilution of blood using albumin and crystalloid can be used in cardiopulmonary bypass surgery. FLEXBUMIN 5% is indicated as a component of the pump prime during cardiopulmonary bypass procedures.

1.4 Limitations of Use

Albumin is not indicated as an intravenous nutrient.

2 DOSAGE AND ADMINISTRATION

For intravenous use only.

2.1 Dose

The dose required depends on the patient's body weight, severity of injury/illness and on continuing fluid and protein losses. Adjust the concentration, dosage and infusion rate to the patient's individual requirements. Use adequacy of circulating blood volume, not plasma albumin levels, to determine the dose required. Refer to Table 1 for recommended doses.

Do not exceed 2 g of albumin per kg of body weight for the daily dose. Do not exceed 1 mL/min for patients with normal blood volume. More rapid administration can cause circulatory overload and pulmonary edema. [See Warnings and Precautions (5.2)]

3 DOSAGE FORMS AND STRENGTHS

FLEXBUMIN 5% is a solution containing 5 g of albumin per 100 mL.

4 CONTRAINDICATIONS

- Patients with a history of hypersensitivity reaction to albumin preparations or to any of the excipients (N-acetylcysteine and sodium caprylate).
- Hypersensitivity reactions (including anaphylactic reactions) have been observed.

5 WARNINGS AND PRECAUTIONS

5.1 Hypersensitivity Reactions

Hypersensitivity reactions (including anaphylactic reactions) have been observed. Discontinue administration immediately if a hypersensitivity reaction (including anaphylactoid type reactions) is suspected. In case of shock, implement standard medical treatment for shock.

5.2 Hypervolemia/Hemodilution

Under conditions where hypervolemia and/or hemodilution may occur, adjust dose and rate of infusion to the patient's volume status. Monitor coagulation and hematologic parameters when comparatively large volumes are replaced. Ensure adequate substitution of other blood constituents (coagulation factors, platelets, and erythrocytes). Monitor electrolyte status to maintain the electrolyte balance. Discontinue administration at the first clinical signs of cardiovascular overload (e.g., headache, dyspnea, jugular venous distention, rales and abnormal elevations in systemic or central venous blood pressure).

Conditions that pose increased risk of hypervolemia and/or hemodilution include but are not limited to:

- Heart failure
- Hypertension
- Esophageal varices
- Pulmonary edema
- Hemorrhagic diathesis
- Severe anemia
- Renal failure

5.3 Hemodynamics

Closely monitor hemodynamic parameters after administrating FLEXBUMIN 5% for evidence of cardiac or respiratory failure, renal failure or increasing intracranial pressure.

5.4 Blood Pressure

Monitor blood pressure in trauma patients and postoperative surgery patients resuscitated with FLEXBUMIN 5% in order to detect re-bleeding secondary to clot disruption.

### Table 1

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Hypovolemia

Reversing hypovolemia depends largely upon its ability to draw interstitial fluid into the circulation. It is most effective in patients who are well hydrated. Use 5% protein solutions or dilute 25% albumin with crystalloid solutions in the absence of adequate or excessive hydration.

Hypoalbuminemia

If albumin deficit is the result of excessive protein loss, the effect of FLEXBUMIN 5% will be temporary unless the underlying disorder is reversed.

2.2 Administration

- Visually inspect parenteral drug product for particulate matter and discoloration prior to administration. FLEXBUMIN 5% is a transparent or slightly opalescent solution, which may have a greenish tint or may vary from a pale straw to an amber color. Do not use unless solution is clear of particulate matter or if the solution is turbid.

- Check the container for minute leaks prior to use by squeezing the bag firmly. If leaks are found, discard solution.

- Do not use the bag if the tip protector is damaged, detached or missing.

- Do not dilute with Sterile Water for Injection. Acceptable diluents include 0.9% Sodium Chloride or 5% Dextrose in Water. [See Warnings and Precautions (5.5)]

- Do not mix or add with other medicinal products including blood and blood components, protein hydrolysates or solutions containing alcohol. Do not add supplementary medication.

- Administer within 4 hours after the container has been entered.

- Monitor hemodynamic parameters in patients receiving FLEXBUMIN 5% and check for the risk of hypervolemia and cardiovascular overload. [See Warnings and Precautions (5.2)]

- Record the name and batch number of the product to maintain a link between the patient and the product.

- Discard unused portion.

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

1. Suspend container from eyelet support.
2. Remove plastic protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying the administration set.

### Hypovolemic Shock

- Infants and young children: 12 to 20 mL per kg body weight. Older children and adults: initial dose 250 to 500 mL. Repeat after 15 to 30 minutes if response is not adequate.

### Hypoalbuminemia

- Calculate the body albumin compartment to be 80 to 100 mL per kg body weight. Do not exceed a daily dose of 2 g of albumin per kg of body weight.

### Burns

- The dosage should be determined according to the patient's condition and response to treatment after the first 24 hours.
FLEXBUMIN 5% [Albumin (Human)], USP, 5% Solution

5.5 Hemolysis
Do not dilute FLEXBUMIN 5% with Sterile Water for Injection as this can cause hemolysis in recipients. There exists a risk of potentially fatal hemolysis and acute renal failure from the use of Sterile Water for Injection as a diluent for Albumin (Human). [See Dosage and Administration (2.2)]

5.6 Transmission of Infectious Agents
FLEXBUMIN 5% is a derivative of human blood. Based on effective donor screening and product manufacturing processes, it carries a 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 licensed albumin. The following adverse reactions have been reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

6 ADVERSE REACTIONS
The most serious adverse reactions are hypersensitivity reaction (including anaphylactic reaction) and pulmonary edema.

6.1 Clinical Trials Experience
No sponsor initiated clinical studies have been conducted with FLEXBUMIN 5%.

6.2 Postmarketing Experience
The following adverse reactions have been identified during post-approval use of FLEXBUMIN 5%. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

The following adverse reactions have been reported in the post approval use of FLEXBUMIN 5%:

- Immune System Disorders: Anaphylactic shock, anaphylactic reaction, hypersensitivity/allergic reactions
- Nervous System Disorders: Headache, dysgeusia
- Cardiac Disorders: Myocardial infarction, atrial fibrillation, tachycardia
- Vascular Disorders: Hypotension, flushing
- Respiratory, Thoracic, and Mediastinal Disorders: Pulmonary edema, dyspnea
- Gastrointestinal Disorders: Vomiting, nausea
- Skin and Subcutaneous Tissue Disorders: Urticaria, rash, pruritus
- General Disorders and Administration Site Conditions: Pyrexia, chills

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy
Risk Summary
No human or animal data are available to indicate the presence or absence of drug-associated risk. It is not known whether FLEXBUMIN 5% can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity.

8.2 Lactation
Risk Summary
No human or animal data are available to indicate the presence or absence of drug-associated risk. It is not known whether FLEXBUMIN 5% is excreted in human milk.

8.4 Pediatric Use
The safety of albumin solutions has been demonstrated in children provided the dose is appropriate for body weight; however, the safety of FLEXBUMIN 5% has not been evaluated in sponsor conducted pediatric studies.

8.5 Geriatric Use
No human or animal data.

10 OVERDOSAGE
Hypervolemia may occur if the dosage and rate of infusion are too high. [See Warnings and Precautions (5.2)]

11 DESCRIPTION
FLEXBUMIN 5% is a sterile, nonpyrogenic preparation of albumin in single dosage form for intravenous administration. Each 100 mL contains 5 g of albumin. It has been adjusted to physiological pH with sodium bicarbonate and/or sodium hydroxide and stabilized with N-acetyltryptophan (0.004M) and sodium caprylate (0.004M). The sodium content is 145 ± 15 mEq/L. FLEXBUMIN 5% contains no preservative and none of the coagulation factors found in fresh whole blood or plasma. FLEXBUMIN 5% is a transparent or slightly opalescent solution which may have a greenish tint or may vary from a pale straw to an amber color and is clear of particulate matter.

FLEXBUMIN 5% is manufactured from human plasma by the modified Cohn-Oncley cold ethanol fractionation process, which includes a series of cold-ethanol precipitation, centrifugation and/or filtration steps followed by pasteurization of the final product at 60 ± 0.5°C for 10 - 11 hours. This process accomplishes both purification of albumin and reduction of viruses.

In vitro studies demonstrate that the manufacturing process for FLEXBUMIN 5% provides for effective viral reduction. These viral reduction studies, summarized in Table 2, demonstrate viral clearance during the manufacturing process for FLEXBUMIN 5%.

These studies indicate that specific steps in the manufacturing of FLEXBUMIN 5% are capable of eliminating/inactivating a wide range of relevant and model viruses. Since the mechanism of virus elimination/inactivation by fractionation and by heating steps is different, the overall manufacturing process of FLEXBUMIN 5% is effective in reducing viral load.

### Table 2

<table>
<thead>
<tr>
<th>Process Step</th>
<th>Viral Reduction Factor (log&lt;sub&gt;10&lt;/sub&gt;)</th>
</tr>
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<tr>
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<sup>a</sup> Human immunodeficiency virus type 1 (HIV-1) both as a target virus and model for HIV-2 and other lipid-enveloped RNA viruses; bovine viral diarrhea virus (BVDV), a model for lipid-enveloped RNA viruses, such as hepatitis C virus (HCV); West Nile Virus (WNV), a target virus and model for other similar lipid-enveloped RNA viruses; pseudorabies virus (PRV), a model for other lipid-enveloped DNA viruses such as hepatitis B virus (HBV); minute mouse virus (MMV), models for non-enveloped DNA viruses such as human parvovirus B19<sup>19</sup>; and hepatitis A virus (HAV), a target virus and a model for other non-enveloped RNA viruses.

<sup>b</sup> Other Albumin fractionation process steps (processing of cryo-poor plasma to Fraction I+II+III/II+III supernatant and processing of Fraction V suspension to Cuno 90LP filtrate) showed virus reduction capacity in in vitro viral clearance studies.

<sup>c</sup> Recent scientific data suggests that the actual human parvovirus B19 (B19V) is far more effectively inactivated by pasteurization than indicated by model virus data.<sup>10</sup> The likelihood of the presence of viable hepatitis viruses has been minimized by testing the plasma at three stages for the presence of hepatitis viruses, by fractionation steps with demonstrated virus removal capacity and by heating the product for 10 hours at 60°C. This procedure has been shown to be an effective method of inactivating hepatitis virus in albumin solutions even when those solutions were prepared from plasma known to be infective.<sup>1,2</sup>

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</tbody>
</table>
The minimum plasma albumin level necessary to prevent or reverse peripheral edema is unknown. It is recommended that plasma albumin levels be maintained at approximately 2.5 g/dL. This concentration provides a plasma oncotic pressure value of 20 mmHg.6

15 REFERENCES

16 HOW SUPPLIED/STORAGE AND HANDLING
FLEXBUMIN 5% is supplied in a single-dose plastic container:

<table>
<thead>
<tr>
<th>NDC Number</th>
<th>Fill Size</th>
<th>Grams Protein</th>
</tr>
</thead>
<tbody>
<tr>
<td>NDC 0044-0495-05</td>
<td>250 mL</td>
<td>12.5 g</td>
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</table>

Storage
Room temperature: not exceed 30°C (86°F). Protect from freezing.

17 PATIENT COUNSELING INFORMATION
- Inform patients of the early signs of hypersensitivity reactions, including hives, generalized urticaria, chest tightness, dyspnea, wheezing, faintness, hypotension, and anaphylaxis. [See Warning and Precautions (5.1)].
- Inform patients that FLEXBUMIN 5% is made from human plasma and may contain infectious agents that can cause disease (e.g., viruses and, theoretically, the CJD agent). Explain that the risk of FLEXBUMIN 5% transmitting an infectious agent has been reduced by screening the plasma donors, by testing the donated plasma for certain virus infections, and by a process demonstrated to inactivate and/or remove certain viruses during manufacturing. Symptoms of a possible virus infection include headache, fever, nausea, vomiting, weakness, malaise, diarrhea, or, in the case of hepatitis, jaundice. [See Warnings and Precautions (5.6)].