### Summary of Viral Reduction Factor for Each Virus and Processing Step

<table>
<thead>
<tr>
<th>Virus</th>
<th>Processing Step</th>
<th>Lipid Enveloped</th>
<th>Non-Lipid Enveloped</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>HIV-1</td>
<td>Flaviviridae</td>
</tr>
<tr>
<td>Fluid</td>
<td>Viral Reduction Factor, log_{10}</td>
<td>&gt; 4.9</td>
<td>&gt; 4.8</td>
</tr>
<tr>
<td></td>
<td>Mean Cumulative Reduction Factor, log_{10}</td>
<td>&gt; 12.7</td>
<td>&gt; 11.3</td>
</tr>
</tbody>
</table>

### Indications and Usage

#### 1. Hypoalbuminemia

Hypoalbuminemia is a possible indication for use of FLEXBUMIN 25%. It is effective in reversing hypovolemia and is recommended prior to or during cardiopulmonary bypass surgery, as it has been recommended in patients with severe nephrosis. It is also effective in treating edema in patients with severe nephrosis.
FLEXBUMIN 25% must be administered intravenously. The rate of administration should be adjusted according to the solution concentration and the patient's hemodynamic measurements and should not exceed 1 mL/min to patients with normal blood volume. More rapid administration might cause circulatory overload and pulmonary edema. At the first clinical signs of cardiovascular overload (headache, dyspnea, jugular vein congestion), or increased blood pressure, raised central venous pressure and pulmonary edema, the infusion is to be stopped immediately.

Blood Pressure
A rise in blood pressure after 25% albumin infusion necessitates careful observation of the injured or post-operative patient in order to detect and treat severe blood vessels that may not have bled at a lower blood pressure.

Pregnancy—Category C, and Lactation
There are no adequate data from the use of FLEXBUMIN 25% in pregnant or lactating women. Animal reproduction studies have not been conducted with FLEXBUMIN 25%. It is not known whether FLEXBUMIN 25% can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Physicians should carefully consider the potential risks and benefits for each specific patient before prescribing FLEXBUMIN 25%. FLEXBUMIN 25% should be given to a pregnant woman only if clearly needed.

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 25% has not been evaluated in pediatric patients.

Large Volumes
If comparatively large volumes are to be replaced, controls of coagulation and hematocrit are necessary. Care must be taken to ensure adequate substitution of other blood constituents (coagulation factors, electrolytes, platelets, and erythrocytes). Appropriate hemodynamic monitoring should be undertaken.

Electrolyte Status
When FLEXBUMIN 25% is given, the electrolyte status of the patient should be monitored and appropriate steps taken to restore or maintain the electrolyte balance.

DRUG INTERACTIONS
No interaction studies have been performed with FLEXBUMIN 25%.

ADVERSE REACTIONS
Adverse Reactions from Clinical Trials
There are no data available on adverse reactions from clinical trials conducted with FLEXBUMIN 25%.

Post-Marketing Adverse Reactions
The following adverse reactions have been reported in the post-marketing experience. These reactions are listed by MedDRA System Organ Class (SOC), then by Preferred Term in order of severity.

IMMUNE SYSTEM DISORDERS: Anaphylactic shock, Anaphylactic reactions, Hypersensitivity/Allergic reactions
NERVOUS SYSTEM DISORDERS: Headache
CARDIAC DISORDERS: Tachycardia
VASCULAR DISORDERS: Hypotension, Flushing
RESPIRATORY, THORACIC, AND MEDIASTINAL DISORDERS: Dyspnea
GASTROINTESTINAL DISORDERS: Vomiting, Nausea, Dysgeusia
SKIN AND SUBCUTANEOUS TISSUE DISORDERS: Urticaria, Rash, Pruritus
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS: Pyrexia, Chills

Overdose
Hypervolemia may occur if the dosage and rate of infusion are too high. (See Precautions: Hypervolemia/Hemodilution)

DOSAGE AND ADMINISTRATION
FLEXBUMIN 25% must be administered intravenously. Do not use if turbid. Do not begin administration more than 4 hours after the container has been entered. Discard unused portion.

FLEXBUMIN 25% solutions must not be diluted with Sterile Water for Injection as this may cause hemolysis in recipients (see CONTRAINDICATIONS). Albumin solutions should not be mixed with other medicinal products including blood and blood components, but can be used concomitantly with other parenterals such as whole blood, plasma, saline, glucose or sodium lactate when deemed medically necessary. The addition of four volumes of normal saline or 5% glucose to 1 volume of FLEXBUMIN 25% gives a solution, which is approximately isotonic and isosmotic with citrated plasma.

Albumin solutions should not be mixed with protein hydrolysates or solutions containing alcohol since these combinations may cause the proteins to precipitate. Do not add supplementary medication. Hypervolemia may occur if the dosage and rate of infusion are not adjusted, giving consideration to the solution concentration and the patient's clinical status. Hemodynamic parameters should be monitored in patients receiving FLEXBUMIN 25% and should be used to check for the risk of hypervolemia and cardiovascular overload. (See PRECAUTIONS).

It is strongly recommended that every time that FLEXBUMIN 25% is administered to a patient, the name and batch number of the product be recorded in order to maintain a link between the patient and the batch of the product.

Recommended Dosages
1. Hypovolemic Shock
   The dosage of FLEXBUMIN 25% must be individualized. As a guideline, the initial treatment should be in the range of 100 to 200 mL for adults and 2.5 to 5 mL per kilogram body weight for children. This may be repeated after 15 to 30 minutes, if the response is not adequate. For patients with significant plasma volume deficits, albumin replacement is best administered in the form of 5% Albumin (Human).
   Upon administration of additional albumin or if hemorrhage has occurred, hemodilution and a relative anemia will follow. This condition should be controlled by the supplemental administration of compatible red blood cells or compatible whole blood.

2. Burns
   The optimal therapeutic regimen for administration of crystalloid and colloid solutions after extensive burns has not been established. When FLEXBUMIN 25% is administered after the first 24 hours following burns, the dose should be determined according to the patient’s condition and response to treatment.

3. Hypoalbuminemia
   Hypoalbuminemia is usually accompanied by a hidden extravascular albumin deficiency of equal magnitude. This total body albumin deficit must be considered when determining the amount of albumin necessary to reverse the hypoalbuminemia. When using patient’s serum albumin concentration to estimate the deficit, the body albumin compartment should be calculated to be 80 to 100 mL per kg of body weight. Daily dose should not exceed 2 g of albumin per kilogram of body weight.

4. Hemolytic Disease of the Newborn
   FLEXBUMIN 25% may be administered prior to or during exchange transfusion in a dose of 1 g per kilogram body weight.

Preparation for Administration
Check the GLOBAL CATHETER for minute leaks prior to use by squeezing the bag firmly. If leaks are found, discard solution as sterility may be impaired. Do not add supplementary medication. Do not use unless solution is clear of particulate matter and seal is intact. FLEXBUMIN 25% is a transparent or slightly opalescent solution, which may have a greenish tint or may vary from a pale straw to an amber color. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

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 the fluid from the secondary container is complete.

Administration
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 set. Make certain that the administration set contains an adequate filter (15-micron or smaller).

HOW SUPPLIED
FLEXBUMIN 25% is supplied in 50 mL (NDC 0944-0493-01) and 100 mL (NDC 0944-0493-02) in single dose GALAXY plastic container (PL 2501).

STORAGE
Store FLEXBUMIN 25% at room temperature, not to exceed 30°C (86°F). Protect from freezing.

REFERENCES

Baxter Healthcare Corporation
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