PRODUCT MONOGRAPH

BUMINATE 5%
BUMINATE 25%

Albumin (Human), USP

5% Solution for Infusion
25% Solution for Infusion

Blood Product/ Human Plasma Derivative

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Date of Approval:
March 12, 2013

Submission Control No: 160731, 160732

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PART I: HEALTH PROFESSIONAL INFORMATION

SUMMARY PRODUCT INFORMATION

Route of Administration	Dosage Form / Strength	Clinically Relevant Nonmedicinal Ingredients
Intravenous	Solution for infusion: 5% and 25%	None of the nonmedicinal ingredients are clinically relevant. The sodium content is 145 ± 15 mEq/L. *For a complete listing see Dosage Forms, Composition and Packaging section.*

DESCRIPTION

BUMINATE 5%, Albumin (Human), 5% Solution and BUMINATE 25%, Albumin (Human), 25% Solution are sterile, nonpyrogenic preparations of albumin in a single dosage form for intravenous administration prepared from human venous plasma using the Cohn-Oncley cold ethanol fractionation process.

Each 100 mL of BUMINATE 5% contains 5 g of albumin.

Each 100 mL of BUMINATE 25% contains 25 g of albumin.

This product is prepared from large pools of human plasma, which may contain the causative agents of hepatitis and other viral diseases (see WARNINGS AND PRECAUTIONS). 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 10-11 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[1, 2, 3] (see PHARMACEUTICAL INFORMATION, Viral Inactivation).

BUMINATE 5% and BUMINATE 25% contain no blood group isoagglutinins thereby permitting administration without regard to the recipient's blood group.

INDICATIONS AND CLINICAL USE

1. Hypovolemia

   Hypovolemia is a possible indication for BUMINATE 5% and BUMINATE 25%. Its effectiveness in reversing hypovolemia depends largely upon its ability to draw interstitial fluid into the circulation. It is most effective with patients who are well hydrated.

   When hypovolemia is long-standing and hypoalbuminemia exists accompanied by adequate hydration or edema, 25% albumin is preferable to 5% protein solutions.[4, 6] However, in the absence of adequate or excessive hydration, 5% protein solutions should be used or 25% Albumin should be diluted with crystalloid.

   Although crystalloid solutions and colloid-containing plasma substitutes can be used in emergency treatment of shock and in other similar conditions where the restoration of blood volume is urgent, Albumin (Human) has a prolonged intravascular half-life.[9, 15] When blood volume deficit is the result of hemorrhage, compatible red blood cells or whole blood should be administered as quickly as possible.

   Recent studies have provided additional information suggesting that the use of albumin neither increases nor decreases mortality, compared to normal saline, when used for treatment of hypovolemic patients.[25]

2. Hypoalbuminemia

   A. General

   Hypoalbuminemia is another possible indication for use of BUMINATE 5% or BUMINATE 25%. Hypoalbuminemia can result from one or more of the following: [5, 15, 19, 20, 21, 31, 32]

   (1) Inadequate production (malnutrition, burns, major injury, infections, etc.)

   (2) Excessive catabolism (burns, major injury, pancreatitis, etc.)

   (3) Loss from the body (hemorrhage, excessive renal excretion, burn exudates, etc.)

   (4) Redistribution within the body (major surgery, various inflammatory conditions, etc.)

   When albumin deficit is the result of excessive protein loss, the effect of administration of albumin will be temporary unless the underlying disorder is reversed. In most cases, increased nutritional replacement of amino acids and/or protein with concurrent treatment of the underlying disorder will restore normal plasma albumin levels more effectively than albumin solutions. Occasionally hypoalbuminemia accompanying severe injuries, infections or pancreatitis cannot be quickly reversed and nutritional supplements may fail to restore serum albumin levels. In these cases, BUMINATE 5% or BUMINATE 25% might be a useful therapeutic adjunct.[22]

   B. Burns

   An optimum regimen for the use of albumin, electrolytes and fluid in the early treatment of burns has not been established, however, in conjunction with appropriate crystalloid therapy, BUMINATE 5% or BUMINATE 25% may be indicated for treatment of oncotic deficits after the initial 24 hour period following extensive burns and to replace the protein loss which accompanies any severe burn.[4, 6, 18, 26, 27, 28, 29] In severe burns immediate therapy in the first 24 hours must include large volumes of crystalloid solutions.

C. Adult Respiratory Distress Syndrome (ARDS) –BUMINATE 25% A characteristic of ARDS is a hypoproteinemic state, which may be causally related to the interstitial pulmonary edema. Although uncertainty exists concerning the precise indication of albumin infusion in these patients, if there is a pulmonary overload accompanied by hypoalbuminemia, 25% albumin solution may have a therapeutic effect when used with a diuretic.[4, 20, 21, 22, 37]

D. Nephrosis – BUMINATE 25% may be a useful aid in treating edema in patients with severe nephrosis who are receiving steroids and/or diuretics.[4, 23, 24]

3. Cardiopulmonary Bypass Surgery – BUMINATE 5% or BUMINATE 25% have been recommended prior to or during cardiopulmonary bypass surgery, although no clear data exist indicating its advantage over crystalloid solutions.[4, 6, 10, 16, 17, 30, 33, 34, 35, 36, 38]

There is no valid reason for use of Albumin as an intravenous nutrient.

CONTRAINDICATIONS

- Albumin administration must not be diluted with water for injections as this may cause hemolysis in recipients. There exists a risk of potentially fatal hemolysis and acute renal failure from inappropriate use of Sterile Water for Injection as a diluent for BUMINATE 5% and BUMINATE 25%.
- Patients with a history of allergic reactions to albumin or to any of the excipients or components of the container (see DOSAGE FORMS, COMPOSITION AND PACKAGING).
- Patients with a history of an incompatibility reaction to such preparations (see ADVERSE REACTIONS).
- Patients with cardiac failure, pulmonary edema or severe and chronic anemia because of the risk of acute circulatory overload.
- Patients with chronic renal insufficiencies due to the potential for accumulations of aluminum; BUMINATE 5% and BUMINATE 25% have been reported to contain trace amounts of aluminum[11, 12] and accumulations of aluminum in patients with chronic renal insufficiencies have led to toxic manifestations such as hypercalcemia, vitamin D-refractory osteodystrophy, anemia, and severe progressive encephalopathy.[12, 13, 14] Therefore, when large volumes of BUMINATE 5%, Albumin (Human), 5% Solution or BUMINATE 25%, Albumin (Human), 25% Solution are contemplated for administration to such patients, serious consideration of these potential risks relative to the anticipated benefits should be given.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

- Risk of transmitting infectious agents (see General section below)
- Must not be diluted with water for injection (see General section below; see also CONTRAINDICATIONS and DOSAGE AND ADMINISTRATION)

The physician should discuss the risks and benefits of this product with the patient, before administering to the patient (see General section below).

General

Because this product is made from human plasma, a risk of transmitting infectious agents, e.g., viruses and, theoretically, the agent that causes Creutzfeldt-Jakob Disease (CJD) in humans, cannot be totally excluded. This also applies to unknown or emerging viruses and other pathogens.

The risk of transmitting an infectious agent has been reduced by screening plasma donors for prior exposure to certain viruses, by testing for the presence of certain current virus infections, and by inactivating and/or removing certain viruses. The measures taken are considered effective for enveloped viruses such as HIV, HBV, and HCV, and for the non-enveloped viruses HAV and Parvovirus B19. (see PHARMACEUTICAL INFORMATION, Viral Inactivation)

Despite these measures, such products could still transmit disease. Based on effective donor screening and product manufacturing processes, the risk for disease transmission is considered extremely remote. No confirmed cases of transmission of viral diseases (including HIV, HBV, HCV, HAV, Parvovirus B19) or CJD have been reported for Albumin.

ALL infections thought by a physician to have been possibly transmitted by this product, should be reported by the physician, or other healthcare provider to Baxter Healthcare Corporation at 1-800-423-2862. It is strongly recommended that every time that Albumin (Human) is administered to a patient, the name and batch number of the product are recorded in order to maintain a link between the patient and the batch of the product.

Albumin (Human) solutions must not be diluted with water for injection. There exists a risk of potentially fatal hemolysis and acute renal failure from the inappropriate use of Sterile Water for Injection as a diluent for Albumin (Human). Acceptable diluents include 0.9% sodium chloride or 5% dextrose in water. (see DOSAGE AND ADMINISTRATION)

Certain components used in the packaging of this product contain natural latex which may cause allergic reactions.

Cardiovascular

Hemodynamics:
Do not administer without very close monitoring of hemodynamics; look for evidence of cardiac or respiratory failure, renal failure, or increasing intra-cranial pressure.

Hypervolemia/Hemodilution:

Albumin (Human) should be used with caution in conditions where hypervolemia and its consequences or hemodilution could represent a special risk for the patient. Examples of such conditions are:

- Decompensated cardiac insufficiency
- Hypertension
- Esophageal varices
- Pulmonary edema
- Hemorrhagic diathesis
- Compensated severe chronic anemia
- Severe anemia
- Renal and post-renal failure
- Brain edema

The rate of administration should be adjusted according to the solution concentration and the patient's hemodynamic measurements (see DOSAGE and ADMINISTRATION). Rapid administration might cause circulatory overload and pulmonary edema.[40] At the first clinical signs of cardiovascular overload (increased respiratory rate, laboured breathing, tachycardia, rales on auscultation of the lungs, headache, dyspnea, jugular vein congestion), or increased blood pressure, raised central venous pressure and pulmonary edema, the infusion is to be stopped immediately and patient's hemodynamic parameters carefully monitored.

When BUMINATE 5% is used following injuries or surgery, the quick rise in blood pressure which follows administration makes it necessary to monitor the patient to detect and treat severed blood vessels that may not have bled at a lower blood pressure. Patients should always be carefully monitored to guard against circulatory overload.

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

Immune

Suspicion of allergic or anaphylactic type reactions requires immediate discontinuation of the injection. In case of shock, standard medical treatment for shock should be implemented.

Renal

Not recommended for administration to dialysis patients.

Use with caution in patients with renal and post-renal failure (see Cardiovascular, Hypervolemia/Hemodilution above).

Special Populations

The effects of Albumin on fertility have not been established in controlled clinical trials.

Pregnant Women: There are no adequate data from the use of BUMINATE 5% and BUMINATE 25% in pregnant women. Physicians should carefully consider the potential risks and benefits for each specific patient before prescribing Albumin (Human).

Nursing Women: There are no adequate data from the use of BUMINATE 5% or BUMINATE 25% in lactating women. BUMINATE 5% or BUMINATE 25% should only be administered to Lactating women if the benefit clearly outweighs any potential risk to the nursing infant.

Pediatrics: The safety and effectiveness of BUMINATE 5% or BUMINATE 25% solution has not been established in pediatric patients, but no risks additional to those seen in adults have been identified when BUMINATE 5% or BUMINATE 25% solution has been administered to these patients.

Buminate Albumin (Human) solutions are not recommended for administration to infants.[11, 12, 13, 14]

Geriatrics: No studies have been conducted to evaluate the safety and effectiveness in the geriatric population.

Monitoring and Laboratory Tests

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 Albumin (Human) is given, the electrolyte status of the patient should be monitored and appropriate steps taken to restore or maintain the electrolyte balance.

Blood pressure

A rise in blood pressure after Albumin (Human) infusion necessitates careful observation of the injured or post-operative patient in order to detect and treat severed blood vessels that may not have bled at a lower blood pressure.

ADVERSE REACTIONS

Clinical Trial Adverse Drug Reactions

There are no data available on adverse reactions from Baxter-sponsored clinical trials conducted with BUMINATE 5% or BUMINATE 25%.

Post-Market Adverse Drug Reactions

The following adverse reactions have been reported in the post-marketing experience. These reactions are listed by MedDRA System Organ Class (SOC) Version 15.0, then by Preferred Term in order of severity.

IMMUNE SYSTEM DISORDERS: Anaphylactic shock, Anaphylactic reactions, 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, Pruritis

GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS:

Pyrexia, Chills

DRUG INTERACTIONS

No interaction studies have been performed with Albumin (Human).*

*None known based upon the absence of data from clinical trials, literature searches, and safety reports.

DOSAGE AND ADMINISTRATION

Dosing Considerations

- Dosage must be individualized.
- Solution must be administered intravenously.
- Albumin (Human) 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, dextrose or sodium lactate when deemed medically necessary.
- Albumin (Human) 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.
- Patient should receive adequate hydration.
- Monitor the patient and adjust the dosage and rate of infusion to the patient's circulatory situation to guard against circulatory overload and hypervolemia.
- Ensure adequate substitution of other blood constituents (coagulation factors, electrolytes, platelets and erythrocytes), if large volumes are to be replaced.
- Monitor hemodynamic performance regularly; this may include:
  - arterial blood pressure and pulse rate
  - central venous pressure
  - pulmonary artery wedge pressure
  - urine output
  - electrolyte
  - hematocrit/hemoglobin
- BUMINATE 5% may be administered rapidly to individuals with reduced plasma volume except if patient has a history of cardiac or circulatory disease (should be administered slowly at 5 to 10 mL per minute to avoid too rapid a rise in the blood pressure).
- BUMINATE 25% must be administered intravenously at a rate not to exceed 1 mL/min to patients with normal blood volume. More rapid administration might cause circulatory overload and pulmonary edema.
- BUMINATE 5% and BUMINATE 25% solutions must not be diluted with water for injection as this may cause hemolysis in recipients. (See CONTRAINDICATIONS)

Recommended Dose and Dosage Adjustment

The concentration of the albumin preparation, dosage and the infusion-rate should be adjusted to the patient's individual requirements. The dose required depends on the size of the patient, the severity of trauma or illness and on continuing fluid and protein losses.

Measures of adequacy of circulating volume and not plasma albumin levels should be used to determine the dose required.

The quantity of BUMINATE 5% given may be increased to a total of 1.0 g albumin per kilogram of body weight (i.e. 20 mL per kilogram), but administration should be monitored by careful observation of the patient.

The addition of four volumes of normal saline or 5% dextrose to 1 volume of BUMINATE 25% gives a solution, which is approximately isotonic and isosmotic with citrated plasma.

In the absence of active hemorrhage, the total dose of BUMINATE 25% should not exceed the normal circulating albumin mass, i.e. 2 grams per kg body weight.

1. Hypovolemia/Hypovolemic Shock

   For patients with significant plasma volume deficits, albumin replacement is best administered in the form of BUMINATE 5%

   The initial dose of BUMINATE 5% administered should be 250 to 500 mL for older children and adults and 12 to 20 mL per kilogram of body weight for young children. It may be repeated after 30 minutes intervals if the response is not adequate.

   For BUMINATE 25%, 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.

   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 BUMINATE 5% is administered after the first 24 hours following burns, an initial dose of 500 mL is recommended.

   When BUMINATE 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.

Administration

Do not use unless solution is clear of particulate matter and seal is intact. BUMINATE 5% and BUMINATE 25% are a transparent or slightly opalescent solutions that 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.

This product must not be used after the expiry date given on the label.

Do not use if turbid.

1. Remove cap from bottle to expose center portion of rubber stopper.
2. Clean stopper with germicidal solution

Follow directions for use printed on the administration set container. Make certain that the administration set contains an adequate filter (15-micron or smaller).

Do not begin administration more than 4 hours after the container has been entered.

Discard unused portion.

OVERDOSAGE

Hypervolemia may occur if the dosage and rate of infusion are too high. (See WARNINGS AND PRECAUTIONS, Cardiovascular)

ACTION AND CLINICAL PHARMACOLOGY

Mechanism of Action

Albumin is responsible for 70-80% of the colloid osmotic pressure of normal plasma, thus making it useful in regulating the volume of circulating blood.[4, 5, 6] Albumin is also a transport protein and binds naturally occurring, therapeutic and toxic materials in the circulation.[5, 6]

Pharmacodynamics

BUMINATE 5% is osmotically equivalent to an equal volume of normal human plasma and will increase circulating plasma volume by an amount approximately equal to the volume infused.

BUMINATE 25% is osmotically equivalent to approximately five times its volume of human plasma. When injected intravenously, 25% albumin will draw about 3.5 times its volume of additional fluid into the circulation within 15 minutes, except when the patient is markedly dehydrated. This extra fluid reduces hemoconcentration and blood viscosity.

Pharmacokinetics

Total body albumin is estimated to be 350 g for a 70 kg man and is distributed throughout the extracellular compartments; more than 60% is located in the extravascular fluid compartment. The half-life of albumin is 15 to 20 days with a turnover of approximately 15 g per day.[5]

The minimum plasma albumin level necessary to prevent or reverse peripheral edema is unknown. Some investigators recommend that plasma albumin levels be maintained at approximately 2.5 g/dL. This concentration provides a plasma oncotic value of 20 mm Hg.[4]

Duration of Effect

The degree and duration of volume expansion depends upon the initial blood volume. With patients treated for diminished blood volume, the effect of infused albumin may persist for many hours; however, in patients with normal volume, the duration will be shorter.[7, 8]

STORAGE AND STABILITY

Store at room temperature, not to exceed 30°C (86°F). Avoid freezing to prevent damage to the bottle.

Stability testing for BUMINATE e 25% showed that aluminum concentration increased over time reaching levels that could exceed 1000 ppb over the shelf life of the product. (See CONTRAINDICATIONS) [41, 42]

DOSAGE FORMS, COMPOSITION AND PACKAGING

BUMINATE 5% and BUMINATE 25% are transparent or slightly opalescent solutions, which may have a greenish tint or may vary from a pale straw to an amber colour.

The solutions have been adjusted to physiological pH with sodium bicarbonate and/or sodium hydroxide. BUMINATE 5% is stabilized with N-acetyltryptophan (0.004 M) and sodium caprylate (0.004 M) and BUMINATE 25% is stabilized with N-acetyltryptophan (0.02 M) and sodium caprylate (0.02 M). The sodium content is 145 ± 15 mEq/L. The solutions contain no preservative and none of the coagulation factors found in fresh whole blood or plasma.

BUMINATE 5%, Albumin (Human), 5% Solution is supplied in 250 mL and 500 mL bottles containing 12.5 g or 25.0 g of albumin respectively.

BUMINATE 25%, Albumin (Human), 25% Solution is supplied in 20 mL, 50 mL, and 100 mL bottles containing 5.0 g, 12.5 g or 25.0 g of albumin, respectively.

PART II: SCIENTIFIC INFORMATION

PHARMACEUTICAL INFORMATION

Drug Substance

Proper name:	Albumin Human
Molecular mass:	MW 66, 500 kDa
Structural formula:	The molecule consists of a single long chain of peptides comprising 585 amino acids and has a compact ellipsoid tertiary structure that is stabilized by 17 disulphide bridges. It is stable with respect to physiochemical influences.
Physicochemical properties:	Albumin is a highly soluble, ellipsoidal protein accounting for 70 to 80% of the colloid osmotic pressure of plasma, thus making it useful in regulating the volume of circulating blood.

Product Characteristics

BUMINATE 5% and BUMINATE 25% are prepared from human venous plasma using the Cohn-Oncley cold ethanol fractionation process. Human plasma used in the manufacture of BUMINATE is collected in the United States of America and complies with all international and national requirements for the collection of human blood and plasma by plasmapheresis.

Viral Inactivation

In vitro studies demonstrate that the manufacturing process for BUMINATE 5% and BUMINATE 25% provides for significant viral reduction. These viral reduction studies, summarized in Table 1, demonstrate viral clearance during the manufacturing process for BUMINATE 5% and BUMINATE 25% using human immunodeficiency virus, type 1 (HIV-1) both as a target virus and as model virus 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); mice minute virus (MMV), models for non-enveloped DNA viruses such as human parvovirus B19; hepatitis A virus (HAV), a target virus and a model for other non-enveloped RNA viruses.

These studies indicate that specific manufacturing steps for BUMINATE 5% and BUMINATE 25% 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 is different, the overall manufacturing process of BUMINATE 5% and BUMINATE 25% is robust in reducing viral load.

Table 1 Summary of Viral Reduction Factor for Each Virus and Processing Step						
Process Step	**Viral Reduction Factor (log_{10})**					
	Lipid Enveloped				**Non-Enveloped**	
	HIV-1	***Flaviviridae***		**PRV**	**HAV**	***Parvoviridae***
		BVDV	**WNV**			**MMV**
Processing of Fraction I+II+III/II+III supernatant to Fraction IV-4 Cuno 70CP filtrate*	>4.9	>4.8	>5.7	>5.5	>4.5	3.0
Pasteurization	>7.8	>6.5	n.d.	>7.4	3.2	1.6**
Mean Cumulative Reduction Factor, log_{10}	**>12.7**	**>11.3**	**>5.7**	**>12.9**	**>7.7**	**4.6**

n.d. = not determined

* Other Albumin fractionation process steps (processing of cryo-poor plasma to Fractionation I+II+III/II+III supernatant and filtration of Fraction V suspension) showed significant virus reduction capacity in *in vitro* viral clearance studies. These process steps also contribute to the overall viral clearance robustness of the manufacturing process. However, since the mechanism of virus removal is similar to that of this particular process step, the viral inactivation data from other steps were not used in the calculation of the Mean Cumulative Reduction Factor.

** Recent scientific data suggest that the actual human parvovirus B19 (B19V) is far more effectively inactivated by pasteurization than indicated by model virus data.[39]

CLINICAL TRIALS

The clinical effectiveness of Albumin (Human) has been determined through many years of clinical use and is described in a number of published studies and clinical practice guidelines. This Product Monograph reflects worldwide post-market experience.

DETAILED PHARMACOLOGY

Human albumin is a normal constituent of human plasma. Refer to Product Monograph Part I, ACTION AND CLINICAL PHARMACOLOGY.

TOXICOLOGY

Human albumin is a normal constituent of human plasma. Toxicology studies have not been conducted.

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PART III: CONSUMER INFORMATION

BUMINATE 5%
BUMINATE 25%

Albumin (Human), USP

5% Solution for Infusion
25% Solution for Infusion

This leaflet is part III of a three-part "Product Monograph" published when BUMINATE 5% and BUMINATE 25% were approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about BUMINATE. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:
BUMINATE is used to used to restore and maintain circulating blood volume, for treating a variety of conditions, including shock, burns, low protein levels, and low albumin levels. It may be used for certain conditions as determined by your doctor.

What it does:
BUMINATE works by helping to increase the volume of the blood in the blood vessels.

When it should not be used:
BUMINATE should not be used in the following situations:
- if you are allergic to albumin or to any of the ingredients in the product or to any components of the container.
- if you have heart failure
- if you have fluid accumulation in your lungs
- if you have severe and chronic anemia
- if you have loss of kidney function

What the medicinal ingredient is:
Albumin (Human)

What the important nonmedicinal ingredients are:
The sodium content is 145 ± 15 mEq/L.

For a full listing of nonmedicinal ingredients see Part 1 of the product monograph.

What dosage forms it comes in:
BUMINATE 5% is supplied in 250 mL and 500 mL bottles containing 12.5 g or 25.0 g of albumin respectively.
BUMINATE 25% is supplied in 20 mL, 50 mL, and 100 mL bottles containing 5.0 g, 12.5 g or 25.0 g of albumin, respectively.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

Risk of transmitting infectious agents (because BUMINATE 5% and BUMINATE 25% are made from human plasma, a risk of transmitting infectious agents, such as viruses or other agents that can cause infection, cannot be totally excluded.)

Must not be diluted with water for injection (your doctor will use saline or dextrose solutions if it is necessary to dilute BUMINATE 5% or BUMINATE 25%)

BEFORE you use BUMINATE talk to your doctor or pharmacist if:

you have heart failure, fluid accumulation in your lungs, anemia, or kidney problems

you have high blood pressure, abnormally enlarged veins in the lower part of your esophagus, an abnormal tendency to bleed, or swelling of the brain

you have any allergies to albumin or to any of the ingredients in the product or to any components of the container

you are pregnant or breast feeding

Ask your doctor to discuss the risks and benefits of this product before it is administered to you.

INTERACTIONS WITH THIS MEDICATION

No interactions are known based upon the absence of data from clinical trials, literature searches, and safety reports; however, BUMINATE should be not mixed with other medication.

PROPER USE OF THIS MEDICATION

Usual dose:
Albumin is injected into a vein in the arm and is always given under direct supervision of a doctor, usually in a hospital or clinic setting. The dose and the rate at which this albumin is given vary according to the person's individual needs for plasma albumin, and depend on the condition being treated.

Overdose:
Fluid overload may occur if the dosage and rate of infusion are too high. This could lead to an increase in weight, swelling in the legs and arms, and/or fluid in the abdomen.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:
It is important to use this medication exactly as prescribed by your doctor. If you miss an appointment for your treatment, contact your doctor as soon as possible.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Untoward reactions to BUMINATE are extremely rare, although nausea, fever, chills or hives may occasionally occur. Such symptoms usually disappear when the infusion is slowed or stopped for a short period of time. In isolated cases, anaphylactic reactions or shock may occur. In these cases, the infusion should be stopped immediately and an appropriate treatment instituted. If the dose and infusion rate are too high, fluid overload may occur. Signs that this is happening include headache, uncomfortable awareness of your breathing, rapid heartbeat, increased blood pressure or water in the lungs. Your doctor must immediately stop the infusion and check your blood circulation.

This is not a complete list of side effects. For any unexpected effects while taking BUMINATE, contact your doctor or pharmacist.

HOW TO STORE IT

Store at room temperature, not to exceed 30°C (86°F). Avoid freezing to prevent damage to the bottle.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to:
    Canada Vigilance Program
    Health Canada
    Postal Locator 0701D
    Ottawa, Ontario
    K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be obtained by contacting the sponsor, Baxter Corporation at: 1-800-387-8399.

This leaflet was prepared by Baxter Corporation.

Last revised: March 12, 2013