## 1. NAME OF THE MEDICINAL PRODUCT:

ALBUCEL® is Human Albumin 20% solution for infusion.

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

ALBUCEL-20%® is Human Albumin for Intravenous use. It is a sterile, liquid preparation in aqueous solution.

ALBUCEL-20%® is supplied as single vial with sterile, liquid preparation for injection containing 20 gm of albumin per 100 ml of aqueous solution.

Each vial contains:

| | |
|---|---|
| Concentration Available | 20% |
| Pack Size | 100ml |
| Total Protein | 200 g/I |
| Sodium Caprylate (as stabilizer) | 2.659 g/I |
| Acetyl Tryptophan (as Stabilizer) | 3.940 g/I |
| Na+ Contents | not more than 160 mM/I |
| K+ Contents | not more than 2 mM/I |
| Aluminum Contents | not more than 200 µM/I |

## 3. PHARMACEUTICAL FORM

Sterile liquid preparation in aqueous solution. Solution for infusion.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

*Hypovolemic Shock*

Albucel is a hyperoncotic solution. Albucel is indicated in the emergency treatment of hypovolemia with or without shock associated with blood loss, trauma and surgical procedure. On intravenous infusion, it will expand the plasma volume by an additional amount, three to four times the volume actually

administered, by withdrawing fluid from the interstitial spaces, provided the patient is normally hydrated interstitially or there is interstitial oedema. If the patient is dehydrated, additional crystalloids must be given. The patient's hemodynamic response should always be monitored with usual precautions against circulatory overload. If there has been considerable loss of red blood cells, transfusion with packed red blood cells is indicated. The total dose should not exceed the level of albumin found in the normal individual; i.e., about 2 g per kg body weight in the absence of active bleeding. Albucel with appropriate crystalloids, may offer therapeutic advantages in oncotic deficits or in long-standing shock where treatment has been delayed.

*Burn Therapy*

An optimal therapeutic regimen with respect to the administration of colloids, crystalloids, and water following extensive bums has not been established. During the first 24 hours after sustaining thermal injury, large volumes of crystalloids are infused to restore the depleted extracellular fluid volume. Beyond 24 hours, Albumin is used in conjunction with adequate infusions of crystalloid to counteract hemoconcentration and the hypoproteinemia, electrolytes and water that usually follow severe burns.

*Hypoproteinemia (With or Without Edema)*

Albumin is indicated in the treatment of hypoproteinemia caused by a loss of plasma protein. Loss of plasma protein may occur through decreased absorption in gastrointestinal disorder, inadequate synthesis in chronic liver diseases or excessive urinary catabolism in chronic liver diseases. Albumin serves to restore colloidal osmotic pressure and in, conjugation with a diuretic, promotes diuresis. During major surgery, patients can lose over half of their circulating albumin with the attendant complications

of oncotic deficit. A similar situation can occur in sepsis or intensive care patients. Treatment with Albumin may be of value in such cases.

*Ascites*

Removal of ascitic fluid from a patient with cirrhosis may cause changes in cardiovascular function and even result in hypovolemic shock. In such circumstances, albumin infusion is used to support the blood volume.

*Renal Dialysis*

Although not part of the regular regimen of renal dialysis, Albumin can be used as an adjunct in patients who are undergoing long term hemodialysis and are susceptible to shock or hypotension, or in dialysis patient who are hypovolemic and may not tolerate large volumes of crystalloids infusion as treatment for shock and hypovolemia. The usual volume administered is about 100 mL, taking particular care to avoid fluid overload as these patients are often fluid overloaded and cannot tolerate substantial volumes of salt solution. Albumin solution is suitable for use in dialysis patients, as aluminum content is less than 200 microgms.

*Acute Liver Failure*

In the uncommon situation of rapid loss of liver function with or without coma, administration of Albumin may serve the double purpose of supporting the colloid osmotic pressure of the plasma as well as binding excess plasma bilirubin.

*Neonatal Hemolytic Disease*

The administration of Albumin may be indicated prior to exchange transfusion, in order to bind free bilirubin, thus lessening the risk of kernicterus. Albumin solution is suitable for use in premature babies, as aluminum content is less than 200 microgms.

## 4.2 Posology and method of administration

ALBUCEL® should always be administered intravenously. The total dosage will vary with the individual. Albumin may be administered either undiluted or diluted in 0.9% Sodium Chloride solution (normal saline) or 5% Dextrose in Water. Whenever dilution of albumin human is necessary, the oncotic and osmotic properties as well as the tonicity of the resultant dilution must be considered. If sodium restriction is required, Albumin should only be administered either undiluted or diluted in a sodium-free carbohydrate solution such as 5 % Dextrose in Water. Because of risk of potentially life-threatening hemolysis and acute renal failure, human albumin must not be diluted with sterile water.

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 seventy of trauma or illness and on continuing fluid and protein losses.

If Albumin is to be administered, hemodynamic performance should be monitored regularly. This may include:

- Arterial blood pressure and pulse rate
- Central venous pressure
- Pulmonary artery wedge pressure
- Urine output
- Electrolyte
- Hematocrit/ haemoglobin

Measures of adequacy of circulating volume and not plasma albumin levels should be used to determine the dose required. If large volumes are administered, the product should be warmed to room temperature before use. ln the treatment of shock, an initial dose of 100 mL of the 20% albumin solution is given as rapidly as tolerated. If response within 30 minutes is inadequate, an additional

100 mL of 20% albumin solution may be given. In patient with a slightly low or normal blood volume, the rate of administration should be 1 mL per minute. If more than 250 mL are given, or if haemorrhage has occurred, the administration of packed red blood cells may be desirable.

In severe burns, immediate therapy should include large volumes of crystalloid with lesser amounts of 20% albumin solution to maintain an adequate plasma volume and protein content. After the first 24 hours, the ratio of albumin to crystalloid may be increased to establish and maintain a plasma albumin level of about 2.5 g/100 mL or a total serum protein level of about 5.2 g/100 mL. In acute hypoproteinemia, 250-350 mL of 20% albumin may be required to reduce oedema and to bring serum protein values to normal. Since such patients usually have approximately normal blood volume, the rate of administration should not be greater than 3 ml per minute to avoid circulatory embarrassment.

The initial dosage in children will vary with the clinical state and body weight. A dose one-quarter to one-half the adult dose may be administered, or dosage may be calculated on the basis of 1 - 3 mL of Albumin 20% per kg of body weight. The usual rate of administration in children should be one-quarter the adult rate. For infants suffering from haemolytic disease of the new-born the appropriate dose for binding of free serum bilirubin is 1 gram per kilogram of body weight. This may be administered before or during the exchange procedure. Caution must be observed in hypervolemic infants.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration.

**USE IN SPECIAL POPULATION**

**Pregnancy**

Pregnancy Category C. Animal reproduction studies have not been conducted with Albucel. It is also not known whether Albucel can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Albucel should be given to a pregnant woman only if clearly needed.

**Pediatric Use**

No clinical studies establishing safety and effectiveness of albumin have been conducted in pediatric patients. However, extensive experience in patients suggests that children respond to Albumin in the same manner as adults. There are no known adverse reports of human albumin usage in children, if dose is appropriate for body weight of child.

## 4.3 Contra-indications

Human albumin is contraindicated in certain patients e.g. those with a history of congestive cardiac failure, renal insufficiency or stabilized chronic anaemia. These patients are at special risk of developing circulatory overload. Human albumin is contraindicated in patient with hypersensitivity to albumin preparations or to any of the excipients present in the solution.

## 4.4 Special warnings and special precautions for use

Albumin is made from human plasma. Products made from human plasma may contain infectious agents, such as viruses, and, theoretically, the Creutzfeldt - Jakob Disease (CJD) agent that can cause disease. The theoretical risk for transmission of CJD is considered extremely remote. No cases of transmission of viral diseases or CJD have ever been identified for albumin. The risk that such products will transmit 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 manufacturing

procedure for Albumin includes processing steps designed to further reduce the risk of viral transmission. Albumin is pasteurized in the final container at 60.0 °C for 10 hours. Virus elimination
/inactivation is also achieved by cold alcohol fractionation process. Despite these measures, such products can still potentially transmit disease. There is also the possibility that unknown infectious agents may be present in such products. Individuals who receive infusions of blood or plasma products may develop signs and/or symptoms of some viral infections, particularly hepatitis C. All infections thought by a physician possibly to have been transmitted by this product should be reported by the physician or other healthcare provider. The physician should discuss the risks and benefits of this product with the patient, before prescribing or administering it to the patient. As with any hyper oncotic protein solution likely to be administered in large volumes, severe haemolysis and acute renal failure may result from the inappropriate use of Sterile Water for Injection as a diluent for Albumin 20%. Acceptable diluents include 0.9% Sodium Chloride or 5% Dextrose in Water.

Bottles which are cracked or which have been previously entered or damaged should not be used, as this may have allowed the entry of microorganisms. ALBUCEL® contains no preservative.

Certain solutions containing protein hydrolysates or alcohol must not be infused through the same administration set in conjunction with albumin since these combinations may cause the proteins to precipitate.

Albumin should be administered with caution to patients with low cardiac reserve. Albumin should be used with caution in patients who are at increased risk of developing circulatory overload and its

consequences or hemodilution could represent

a special risk for the patient. Examples of such conditions are:

- Hypertension
- Oesophageal varices
- Pulmonary oedema
- Haemorrhagic diathesis
- Renal and post-renal anuria
- Decompensated cardiac insufficiency
- Severe anemia

Rapid infusion may cause vascular overload with resultant pulmonary oedema. Patients should be closely monitored for signs of increased venous pressure. At the first clinical signs of cardiovascular overload (headache, dyspnoea, jugular vein congestion), or increased blood pressure, raised venous pressure and pulmonary oedema, the infusion is to be stopped immediately. A rapid rise in blood pressure following infusion necessitates careful observation of injured or postoperative patients to detect and treat severed blood vessels that may have bled at a lower pressure.
Patients with marked dehydration require administration of additional fluids. Albumin may be administered with the usual dextrose and saline intravenous solutions.
ALBUCEL® albumin 20 % solution is relatively low in electrolytes compared to the 5% albumin solution. When albumin is given the electrolyte status of the patient should be monitored and appropriate steps taken to restore or maintain the electrolyte balance.

If comparatively large volumes are to be replaced, controls of coagulation and haematocrit are necessary. Care must be taken to ensure adequate substitution of other blood constituents (coagulation factors, electrolytes, platelets and erythrocytes).

## 4.5 Interaction with other medicinal products and other forms of interaction

Albumin is compatible with whole blood, packed red cells, as well as the standard carbohydrate and electrolyte solutions intended for intravenous use. It should, however, not be mixed with protein hydrolysates, amino acid solutions or solutions containing alcohol. Components used in the packaging of Human Albumin are latex-free.

## 4.6 Fertility, pregnancy and lactation

Pregnancy Category C. Animal reproduction studies have not been conducted with Albumin. It is also not known whether Albumin can cause foetal harm when administered to a pregnant woman or can affect reproductive capacity. Albumin should be given to a pregnant woman only if clearly needed.

## 4.7 Undesirable effects

Adverse reactions with albumin are rare. These reactions normally disappear rapidly when the infusion rate is slowed down or the infusion is stopped. In case of severe reactions, the infusion should be stopped and an appropriate treatment should be initiated. If administration has been stopped and the patient requires additional Albumin, material from a different lot should be used.

Adverse reactions include:

- Allergic or pyrogenic reaction: anaphylaxis, and hypersensitivity reactions including pyrexia, chills, urticaria, skin rash, pruritus, oedema, erythema, hypotension and bronchospasm.
- Psychiatric: confusional state
- Nervous system: headache
- Cardiac: tachycardia, cardiac failure
- Vascular: hypotension, hypertension, flushing

- Respiratory: dyspnoea
- Gastrointestinal: nausea, vomiting
- Skin and subcutaneous tissue: rash erythematosus, hyperhidrosis

**Reporting of suspected adverse reactions**

Reporting of suspected adverse reactions: Healthcare professionals are requested to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) https://pv.pharmacyboardkenya.org

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmaco-dynamic properties

Albumin is a highly soluble, globular protein (MW 66 kDa), accounting for 70% - 80

% of the colloid osmotic pressure of plasma. Therefore, it is important in regulating the osmotic pressure of plasma. Albumin supplies the oncotic equivalent of approximately 4 times its volume of human plasma. It will increase the circulating plasma volume by an amount approximately 2.5 times the volume infused within 15 minutes, if the recipient is adequately hydrated. This extra fluid reduces hemo- concentration and decreases blood viscosity. The degree and duration of volume expansion depend upon the initial blood volume. When treating patients with diminished blood volume, the effect of infused albumin may persist for many hours. Albumin is also a transport protein and binds naturally occurring, therapeutic, and toxic materials in the circulation. It may be useful in severe haemolytic disease in the neonate who is awaiting exchange transfusion. The infused albumin may reduce the level of free bilirubin in the blood. This could also be of importance in acute liver failure where albumin might serve the dual role of supporting plasma oncotic pressure, as well as binding excessive plasma bilirubin.

### 5.2 Pharmacokinetic properties

Albumin is distributed throughout the extracellular water and more

than 60 % of the body albumin pool is located in the extravascular fluid compartment. The total body albumin in a 70 kg adult is approximately 320 g. Albumin has a circulating life span of 15 - 20 days, with a turnover of approximately 15 g per day. It is convenient to use since no cross-matching is required and the absence of cellular elements removes the danger of sensitization with repeated infusions.

### 5.3 Preclinical safety data

Human albumin is a normal constituent of the human plasma and acts like the physiological albumin.

In animals, single dose toxicity testing is of little relevance and does not permit the evaluation of toxic or lethal doses or of a dose-effect relationship. Repeated dose toxicity testing is impracticable due to the development of antibodies to heterologous protein in animal models.

To date, human albumin has not been reported to be associated with embryo-foetal toxicity, oncogenic or mutagenic potential.

No signs of acute toxicity have been described in animal models.

## 6. Pharmaceutical particulars

### 6.1 List of excipients

Sodium

Caprylate

Acetyl

Tryptophan

### 6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

### 6.3 Shelf life

Three years from the date of manufacture. Do not use after expiry date.

### 6.4 Special precautions for storage

- Store below 25° C.

- Do not begin administration more than 4 hours after the container has been opened and any remnant portions to be discarded. Do not freeze. Do not use if the solution is turbid or any particulate matters are observed.
- Store in the original container to protect from light.

### 6.5 Nature and contents of container

ALBUCEL® is available as 20 % intravenous infusion single dose hermetic container, containing 20 mg/ml human albumin.

## 7. Marketing authorization holder

INTAS PHARMACEUTICALS LTD.
Plot No-496/1 A &B, Sarkhej-Bavla Highway,
Village-Matoda, Taluka-Sanand, Ahmedabad-
382213, Gujarat, INDIA

## 8. Marketing authorization number(s)

H2026/CTD11199/21914

## 9. Date of first authorization/renewal of the authorization

04-02-2026

## 10. Date of revision of the text

04-02-2026