MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

On behalf of the Department of Health

CERTIFICATE OF A PHARMACEUTICAL PRODUCT [1]

This certificate conforms to the format recommended by the World Health Organisation (explanatory notes are attached)

Exporting (certifying) country: UNITED KINGDOM

Importing (requesting) country: INDIA

1 Name and dosage form of the product:

A) In the United Kingdom - Zenalb (TM)-20, Human Albumin 20% Solution, SOLUTION FOR INJECTION 200 GM/L

B) In INDIA - Zenalb (TM)-20, Human Albumin 20% Solution, SOLUTION FOR INJECTION 200 GM/L

1.1 Active ingredient(s) [2] and amount(s) [3] per unit dose:

Active Ingredient(s)	Amount per unit dose
HUMAN ALBUMIN	200 GM/L

For complete qualitative composition including excipients, see attached. [4]

1.2 Is this product licensed to be placed on the market for use in the exporting country? [5] ☑Yes ☐No

1.3 Is this product actually on the market in the exporting country? ☑Yes ☐No

1.4 The product is not on the market in the exporting country because

N/A

Certificate Number: PP051583

SUMMARY OF PRODUCT CHARACTERISTICS

Printed for Certificate of Pharmaceutical Product

1. NAME OF THE MEDICINAL PRODUCT

ZENALB™ 20, a Human Albumin 20% Solution.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredients

Human albumin is prepared from plasma from screened donors. These donors are selected from the USA.

Quantitative Composition

Zenalb®20 is a clear, yellow to green, sterilised solution. It is a low salt solution containing 190-210g/L of plasma protein of which not less than 95% is albumin. The residual proteins are heat stable alpha- and beta- globulins. Zenalb®20 is free from plasma proteins associated with the blood clotting mechanism and blood group antibodies.
Zenalb®20 contains 50-120mmol/L sodium. The assayed sodium content is stated on the label of the bottle. For excipients see section 6.1.

3. PHARMACEUTICAL FORM

Zenalb®20 is a low salt solution (hypotonic, but hyperoncotic) of albumin ready to be administered as an intravenous infusion only.

Clinical Particulars

4.1 Therapeutic Indications

Zenalb®20 is used for restoration and maintenance of circulating blood volume where volume deficiency has been demonstrated, use of a colloid such as albumin is appropriate, and where electrolyte or fluid load requires careful monitoring

4.2 Posology and Method of Administration

Zenalb®20 is given by intravenous infusion. In general the dosage and the infusion-rate should be adjusted to the patient's individual requirements.
In anaphylactic reactions, treatment should follow the current recommendations for shock therapy.

Posology

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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 circulating volume and not only plasma albumin levels, should be used to determine the dose required.

If human albumin is to be administered, one or more of the following variables should be measured frequently to estimate changes in circulating blood volume, cardiac filling pressure and circulatory performance:

- arterial blood pressure and pulse rate
- central venous pressure
- pulmonary artery occlusion pressure
- urine output
- electrolytes

Posology in Paediatric Use:

In children the physiological plasma volume is age dependent. This fact must be taken into account when determining dose volumes.

Administration:

Human albumin is ready for use and is for administration by intravenous infusion only. In patients with greatly reduced blood volume and/or shock, the infusion of Zenalb® 20 should not exceed 120ml/hour. As the clinical state of the patient improves and circulating blood volume is returning to normal, the rate should be reduced to a recommended rate of 1-2ml/minute (60-120ml/hour). The infusion rate should be adjusted according to the individual circumstances and the indication, but should normally not exceed 1-2ml/minute.

If large volumes are administered, the product should be warmed to room or body temperature before use.

4.3 Contra-Indications

Hypersensitivity to albumin preparations. Hypersensitivity to any of the components. All conditions in which hypervolaemia and its consequences (e.g. increased stroke volume, elevated blood pressure) or haemodilution could represent a special risk to the patient.
Examples of such conditions are:

- Decompensated cardiac insufficiency
- Hypertension
- Oesophageal varices
- Pulmonary oedema
- Haemorrhagic diathesis
- Severe anaemia
- Renal and post-renal anuria
- Dehydration (unless sufficient fluid is infused simultaneously)

4.4 Special Warnings and Precautions for Use

Under normal conditions the half-life of albumin is about 19 days. The balance between synthesis and breakdown is normally achieved by feed-back regulation. Elimination is predominantly intracellular and due to lysosome proteases.

In healthy people, less than 10% of infused albumin leaves the intravascular compartment during the first 2 hours following infusion. As a result the circulating volume will increase from 1 to 3 hours after administration. There is considerable individual variation in this effect on plasma volume. In some patients the plasma volume can remain increased for some hours. However, in ill patients albumin can leak out of the vascular space in substantial amounts at an unpredictable rate.

5.3 Preclinical Safety Data

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

In animals, single dose toxicity testing is of little relevance and does not permit the estimation 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-fetal toxicity, oncogenic or mutagenic potential.

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

Pharmaceutical Particulars

6.1 List of Excipients

Sodium range	50-120mmol/L
Potassium upper limit	10mmol/L
Chloride upper limit	40mmol/L
Citrate upper limit	0.1mmol/L
Sodium n-Octanoate range	20-40mmol/L

Zenalb® 20 contains no preservative.

In compliance with the European Pharmacopoeia Zenalb® 20 has an aluminium content of not more than 200µg/L, and is therefore suitable for premature infants and patients undergoing dialysis.

6.2 Incompatibilities

Human albumin should not be mixed with other medicinal products, whole blood and packed red cells. Zenalb®20 has a hyperoncotic effect.