Canine Albumin 5gm/vial

DESCRIPTION

Canine albumin 5gm/vial is a sterile solution of albumin obtained from separation of canine frozen plasma by a modified heat shock method. It is heated to 60°C and concentrated by precipitation and ultrafiltration. Plasma is obtained by the separation of canine whole blood units. Canine donors are DEA typed for 1 and 7, as well as evaluated for warm agglutinating antibodies to known DEA types. All donors have been screened for infectious disease in accordance to the ACVIM Consensus statement 2016.

Purity is determined by gel electrophoresis. Total protein is determined by the Coomassie method. Sterility is confirmed by culture with TFM and Soybean Casein agar. Endotoxin determined by the LAL method. Lots are individually qualified for purity, sterility, potency and identity.

Acceptance criteria for lot release:

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Specification</th>
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<tbody>
<tr>
<td>PURITY</td>
<td>&gt;96% canine albumin</td>
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<tr>
<td>STERILITY-CULTURE</td>
<td>Negative on TFM and Soybean Casein agar</td>
</tr>
<tr>
<td>STERILITY-ENDOTOXIN</td>
<td>&lt;5EU/ml</td>
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<tr>
<td>POTENCY</td>
<td>5gm/vial</td>
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Each 100ml vial contains 5gm of lyophilized albumin. No other additives or preservatives are present.

ADVERSE REACTIONS should be reported to HemoSolutions at info@hemosolutions.com.

CLINICAL PHARMACOLOGY

Canine albumin is osmotically active and useful in the regulation of blood volume. An osmolality of 249 mOsm/kg is expected in the rehydrated product. A pH of 7.1 is expected when rehydrated with sterile water. This product is for intravenous administration.

INDICATIONS AND USE

HYPOPROTEINEMIA  This product may be used as a source of canine albumin.

SHOCK  Albumin may be used in hypovolemic shock where restoration of blood volume is urgent. The primary function of this product is to maintain the colloid osmotic pressure.

CONTRAINDICATIONS

Canine albumin is contraindicated in severely anemic patients or patients demonstrating significant cardiac failure. Patients with a previous history of anaphylaxis secondary to plasma or plasma component exposure should not use this product.

WARNINGS

This product is a lyophilized protein that should be rehydrated with sterile water prior to utilization. The rehydrated product should be transparent. Products made from canine plasma have the risk of containing infectious agents such as viruses, bacteria and/or Rickettsiae which can cause disease. This product is produced from canine plasma that has been screened via PCR and IFA for common infectious diseases to minimize this risk.
PRECAUTIONS

GENERAL Large quantity administrations should be supplemented with a red blood cell containing product to avoid relative anemia. The quick response of blood pressure during the rapid administration of this product may lead to bleeding at points not evident at lower blood pressures. A rapid increase in plasma volume is expected with the administration of this product and the patient should be monitored for hypertension or pulmonary edema.

This product has not been tested in pregnant animals or young animals.

DOSAGE AND ADMINISTRATION

REHYDRATION This product should be rehydrated with sterile water prior to use.

<table>
<thead>
<tr>
<th>Percentage of Albumin</th>
<th>Rehydration volume</th>
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<tbody>
<tr>
<td>5%</td>
<td>95mls sterile water</td>
</tr>
<tr>
<td>15%</td>
<td>30mls sterile water</td>
</tr>
<tr>
<td>25%</td>
<td>18mls sterile water</td>
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</table>

- Store at 4°C after rehydration if not immediately used.
- Discard after 24 hours once rehydrated.

Once rehydrated, the lyophilized powder should be allowed to go into suspension utilizing a gentle swirling motion while avoiding foaming. Rehydration may be quickened by placing the product in a protective plastic sleeve and incubating in a 37°C water bath for 5-10 minutes.

This product may be administered by intravenous injection. Slow infusion is recommended to avoid hypertension and/or relative anemia secondary to blood volume expansion.

Previous published dosing instructions in the dog suggest a dose of 0.8gm/kg for septic peritonitis when using canine specific albumin. A dosing rate of 1ml/min is recommended. The safety study utilized 1gm/kg as an intravenous dose.

STORAGE

Prior to reconstitution, this product may be stored at room temperature (18-24°C). After reconstitution, this product should be refrigerated at 4-6°C if not used.

SAFETY DATA

A safety study was performed in six, normovolemic laboratory Beagles. A dose of 1gm/kg was administered by slow intravenous infusion through a peripheral catheter. Albumin, PCV and COP were measured on Day 0, 1, 2 and 28. No significant adverse reactions were noted.

REFERENCES