EQUIPRIME™

(apheresis-derived allogeneic pooled frozen equine plasma)
For intravenous administration in horses only.
Sterile intravenous bag for single patient use only.

CAUTION:
Federal law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION:
EQUIPRIME™ is an apheresis-derived allogeneic pooled frozen equine plasma intended to provide a species-specific source of plasma for horses. Each single dose bag contains normal equine plasma with sodium citrate as an anticoagulant derived from not more than three healthy donor horses with Aa and Ca erythrocyte antigens present and no common erythrocyte alloantibodies. The product is shipped frozen and maintained at less than or equal to -15°C. This product is shipped frozen in an insulated shipper through standard overnight couriers.

EQUIPRIME™ is yellow to gold and semi-transparent. Plasma contains albumin, plasma proteins, coagulation factors and immunoglobulins consistent with circulating plasma in healthy, well-immunized horses.

INDICATIONS:
EQUIPRIME™ is intended to provide a species-specific source of plasma.

DOSAGE AND ADMINISTRATION:
EQUIPRIME™ is for intravenous administration as a single patient dose. Do not mix this product with other intravenous liquids for administration. Use a standard inline blood filter when administering this product.

Thawing: Thaw quickly in warm water not exceeding 43°C (110°F). DO NOT MICROWAVE.

Dosage: Dose should be determined by the clinician. Administer as soon as thawed by filtered (standard blood filter administration set) intravenous infusion. The initial 50 to 100 mL of EQUIPRIME™ should be administered slowly over 10 to 20 minutes, and the patient should be monitored closely for adverse reactions including tachycardia, tachypnea, fever, piloerection, urticaria, or muscle fasciculations. If these signs are observed the infusion should be stopped. If there are no adverse reactions, the administration rate may be increased. Clinical reports have suggested that 1 L may be safely administered over 20 to 30 minutes, but the clinical state of the patient may warrant slower administration. In no case should the administration rate exceed 60 ml/kg/hr. Do not allow administration of any single unit to exceed 4 hours. Discard any unused portion.

CONTRAINDICATIONS:
EQUIPRIME™ should NOT be used if the patient has been exposed to bovine colostrum as a neonate.

WARNINGS AND PRECAUTIONS

User Safety Warnings:
Not for use in humans. Keep out of reach of children.

Animal Safety Warnings and Precautions:
Allogeneic plasma products such as EQUIPRIME™ may cause transfusion reactions and/or anaphylaxis.

For use in horses only. EQUIPRIME™ has not been tested in donkeys and mules. EQUIPRIME™ is not intended for intra-lesional or intra-articular use.

Allogenic pooled plasma products such as EQUIPRIME™ may carry infectious diseases like equine parvovirus and the potential for transfer between donors and recipient is possible.

ADVERSE REACTIONS:
Anaphylaxis and transfusion reactions such as tachycardia, tachypnea, fever, piloerection, urticaria, and/or muscle fasciculations have been reported with the use of allogeneic plasma products.

CONTACT INFORMATION:
To report suspected adverse events, contact Lake Immunogenics, Inc. at 1-800-648-9990.

STORAGE AND HANDLING:
Store EQUIPRIME™ in a secure freezer with a documented temperature range less than or equal to -15°C (5°F). Thawed product should be used as soon as possible after thawing is complete. Open and unused portions of containers should be discarded.

HOW SUPPLIED:
EQUIPRIME™ is supplied in pharmaceutical grade plastic sterile bags used for intravenous administration. Volumes available include 300ml, 500ml and 1000ml.

INFORMATION FOR HORSE OWNERS:
Owners should be notified that EQUIPRIME™ may have possible side effects including anaphylaxis, transfusion reaction, and disease exposure. Transmission of infectious diseases like equine parvovirus between donors and the recipient is possible.

INFECTIOUS DISEASE RISK MITIGATION:
Donors are vaccinated at least twice annually for Equine Rhinopneumonitis, Equine Influenza, Clostridium botulinum Type B toxoid, Attenuated *Rhodococcus equi*, *Escherichia coli* J-5 strain, West Nile virus, Equine Rotavirus, *Salmonella typhimurium* bacterin toxoid, *Neorickettsia risticii* bacterin, Rabies, Eastern/Western encephalitis, Tetanus toxoid, *Clostridium perfringens* Type C&D, Tetanus, and *Streptococcus equi* bacterial extract.

Donors are tested for Equine Herpes virus Type 1, Equine Infectious anemia, Equine Parvovirus, Babesia caballi, Theileria equi, Brucellosis and Trypanosoma equiperdum prior to entering the closed herd. All donor horses are tested negatively each year for Anaplasmosis, Babesia sp., Bartonella sp., Borrelia sp., EHV-1, EIA, equine parvovirus, Neorickettsia sp. and Rickettsia sp.

Donors are provided continual access to shelter, food and water. Pasture grazing is provided when weather conditions permit.

Each serial is tested negatively by culture for aerobic bacteria, anaerobic bacteria and fungi. This individual product has been tested negatively for Equine Parvovirus-Hepatitis by RT PCR. Release criteria for each serial includes visual inspection, total protein measured by refractometry, confirmation of species using an IgG equine specific reagent, aerobic/anerobic/fungal testing and equine parvovirus RT-PCR using a GMP process.

For a CERTIFICATE OF ASSURANCE email requests to:
sales@lakeimmunogenics.com

MANUFACTURED BY:
Lake Immunogenics, Inc.
Ontario, New York 14519 USA
1-800-648-9990
Website:

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