

HYPERMUNE[®] - RE EQUINE PLASMA

**HYPERMUNE-RE Equine Plasma Plasma for intravenous infusion, after thawing.
For horses (foals 24 hours to 6 days)**

Manufacturing Authorisation Holder: Veterinary Immunogenics Ltd, Carleton Hill, Penrith, Cumbria England CA11 8TZ Tel: +44 1768 863881 Fax: +44 1768 891389 24 Hours: +44 7831 259539

HYPERMUNE-RE is frozen equine plasma for intravenous transfusion after thawing, containing equine IgG \geq 24g/l, equine Total Protein \geq 50g/l, and antibodies to *Rhodococcus equi* \geq 40% VIL standard in a 1 litre human plasma bag. It contains the excipient Acid Citrate Dextrose-A to ensure citrate content 10 - 20mmols/l

Pack size: one litre

Indications:

For foals with Failure of Passive Transfer To raise the level of circulating IgG in neonatal foals which have been shown to have low levels (less than 4g/l). The raised level has been demonstrated approximately 24 hours after administration but the duration of the effect is not known.

For foals with Normal passive Transfer To raise the level of *Rhodococcus equi* antibodies. The raised level has been demonstrated approximately 24 hours after administration and raised levels though declining generally last for up to 21 days.

CONTRAINDICATIONS: None

ADVERSE REACTIONS It should be noted that ACD-A is an excipient and that excess citrate may cause a reaction in the recipient foal. This may be seen as muscle fasciculations, weakness and cardiac abnormalities.

Transfusion Reactions are very rare; signs include tachycardia, hyperventilating and trembling.

Anaphylaxis is very rare, but can occur with products of this nature. Signs include tachycardia, hyperventilating and trembling, or other signs such as colic, pyrexia, cardiac arrhythmias, urticaria and collapse.

Volume Overload is a very rare but possible hazard of plasma transfusion especially if the administration is carried out too quickly. Signs include respiratory distress, hyperventilation, staggering and collapse when in standing restraint. Additionally, if foal is in lateral recumbency froth may be seen at the nostril.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon

TARGET SPECIES: Horses, foals 24 hours to 6 days.

DOSAGE AND METHOD OF ADMINISTRATION:

For foals with Failure of Passive Transfer The dose required is one litre for a 50 kg foal (and pro rata, i.e. 20 ml per kg). Hypermune-RE may be administered to foals from 24 hours to 6 days of age where it has been shown after testing that they have low levels of serum IgG (less than 4 g/l). A blood sample should be collected from the foal approximately 24 hours later and re-tested for the level of serum IgG. If this is still low, a further dose may be administered. This should be given within 24 – 48 hours of the first administration and be given in the same manner as the first (intravenously, via a blood giving set, over 15 - 20 minutes).

For foals with Normal Passive Transfer The dose required is one litre for a 50 kg foal (and pro rata, i.e. 20 ml per kg). To sustain raised levels of circulating *Rhodococcus equi* antibodies a second dose may be given at approximately 21 days later. This should be given in the same manner as the first (intravenously, via a blood giving set, over 15 - 20 minutes).

Advice on correct administration. The required dose is administered via a catheter placed in the jugular vein using a blood giving set equipped with a mesh filter. The product should be administered slowly, particularly at the start, and administration should take 15 – 20 minutes. Throughout the administration, the foal should be monitored for signs of adverse reactions.

Thawing should not take place in a microwave oven. The litre bag of plasma should be immersed only in warm water at not more than 40°C. A water bath such as a sink full of domestic warm water is ideal. As the plasma thaws and the water cools, more warm water may be added as required but hot water (not greater than hand hot) must be avoided as it will damage the proteins. The entire litre of plasma should be brought slowly to body temperature before use to ensure all the cryoprecipitate is dissolved. Under optimum conditions this whole process may take 2-2½ hours. Occasionally small amounts of fibrin may still be seen floating in the plasma. It is not

significant but must be filtered out by the filter in the blood administration set. Inspect for leakage and if apparent on thawing the entire contents must be discarded.

WITHDRAWAL PERIOD: Zero days

SPECIAL PRECAUTIONS FOR STORAGE: Store in a freezer (-30°C to -20°C). HYPERMUNE-RE should be handled carefully when being unpacked and stored in the freezer. The bubble-wrap should not be removed as it protects the brittle frozen plastic which is susceptible to damage from careless handling such as being dropped or knocked in the freezer. When thawed it should be stored in a refrigerator and used within 24 hours. Do not use after the expiry date stated on the label. **Keep out of the reach and sight of children**

SPECIAL WARNINGS: Do not mix with any other medicinal products. It is recommended that no other immunological product be administered within 14 days following administration of HYPERMUNE-RE apart from tetanus antitoxin which may be administered simultaneously but not intravenously. As with colostrum derived passive immunity, the passive immunity transferred by HYPERMUNE-RE may interfere with response to vaccine. It is recommended that this is considered when starting a vaccine programme with due adherence to the vaccine manufacturer's instructions.

It is recommended that appropriate Rhodococcus control measures should be implemented to control disease. Such measures include avoidance of overcrowding, controlling paddock dust levels, provision of shade for the animals, removal of faeces from pastures and close monitoring of foal health.

i) Special Precautions for use in animals

- Do not administer more than 2 doses to an animal.
- If a second dose is required do not administer this before 24 hours.
- To reduce risk of adverse reactions:

Transfusion Reactions. Careful monitoring, especially at the start and throughout the transfusion is essential. Distinction must be made between reaction to restraint and catheterisation and signs attributable to transfusion reaction. If tachycardia, hyperventilating or trembling occurs, the transfusion should be slowed down or stopped altogether. If signs abate within five minutes, as they should, then the transfusion should be continued. If they recur again, the transfusion should be stopped entirely.

Anaphylaxis. Careful monitoring, especially at the start and throughout the transfusion, is essential. If tachycardia, hyperventilating or trembling occurs, the transfusion should be slowed down or stopped altogether. If signs abate within five minutes, as they should, then the transfusion should be continued. If they recur again, the transfusion should be stopped entirely. If severe, or other signs occur such as colic, pyrexia, cardiac arrhythmias, urticaria and collapse, the transfusion should be stopped and if necessary epinephrine (0.01mg/kg), corticosteroids and intravenous saline administered. **These emergency drugs should always be on hand.** Flunixin meglumine at 0.25mg/kg may be used prophylactically to reduce the incidence of side effects.

Volume Overload. Volume overload is a possible hazard of plasma transfusion especially if the administration is carried out too quickly. Careful monitoring throughout the transfusion is essential. If hyperventilating, respiratory distress or trembling occurs, the transfusion should be slowed down or stopped altogether. Diuretics may be used in severe cases.

Do not use in pregnant or lactating horses.

ii) Special Precautions to be taken by the User

Administer only using a blood giving set to minimise risk of self-injection. In case of accidental contact with skin, wash affected areas thoroughly with warm soapy water.

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED OR WASTE PRODUCT: Any unused veterinary medicinal product and administration set or waste materials should be disposed of in accordance with national requirements.

OTHER INFORMATION: From limited field studies there is a trend of reduced severity of *R. equi* disease and a reduced requirement for intensive antibiotic treatment with the use of Hypermune RE by the recommended schedule.

Ireland **VPO** Veterinary Practitioner Only VPA 10662/1/1

POM-V Vm18513/4001 To be supplied only on veterinary prescription in the UK