PlasmaLife® Horse

Leaflet

PLASMALIFE HORSE ®

FRESH FROZEN EQUINE PLASMA

ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Active substances	Quantity
IgG	≥24< 40 g/l
Total proteins	≥50< 90 g/l
Excipients	
ACD-A citrates (expressed as citrate ion)	< 4,73 g/l

INDICATIONS

Equine plasma is used to increase the level of IgG in Hypogammaglobulinemic foals (IgG < 8g/l) in the period between 24 hours and 6 days of age.

CONTRAINDICATIONS

Do not use in case of intolerance to immunoglobulins or contained excipients.
Do not use in species other than the target one.
Do not use in pregnant or lactating mares.
Do not use horses with age other than the authorised one.
Do not use a route of administration other than the intravenous one.

ADVERSE REACTIONS

The risk of adverse reactions to the drug is sporadic. Following administration of equine plasma, immunological reactions of an anaphylactic type could arise due to the presence of red blood cells or protein aggregates. The clinical signs of anaphylactic reactions are characterised by tachycardia, tachypnea, rash, hyperthermia, cardiac arrhythmia, muscle tremors, colic, and collapse. In particular, monitor the cardiac and respiratory parameters of the recipient when the plasma administration starts. A slow infusion at the beginning of the administration allows the receiving foal to show the first signs of reaction at an early stage, to be able to intervene to counteract the reaction itself promptly. If this happens, reduce the speed of administration for 5-10 minutes or interrupt it completely. It is recommended to have epinephrine (0,01 mg/kg), corticosteroids (prednisolone from 0,25 to 1 mg/kg, slow IV), flunixin meglumine (1.1 mg/kg, IV) and intravenous saline solutions available; these must be used by the veterinarian administering the plasma in the case of the occurrence of anaphylactic shock.
However, since both the IgG and other proteins present in the plasma do not degrade and do not clot if the product is stored following the described procedure, the risk of anaphylactic reaction is significantly reduced.
Furthermore, the use of special infusion sets for the transfusion with filters to trap any corpuscular particles present in the plasma almost eliminates this risk.
An excess of citrates can cause muscle twitching, weakness, and heart abnormalities. However, equine plasma contains a negligible amount of these compared to the plasma mass of the recipient, and studies carried in foals from 24 hours to 3 months old, have not shown any problem on this concern.
If you experience any severe adverse reaction or other reactions not mentioned in this package insert, please inform your veterinarian.

TARGET SPECIES

Horses.

DOSAGE, ROUTE AND METHOD OF ADMINISTRATION

The recommended dose of plasma is 20 mL per kilogram of live weight. One litre can be administered to a foal (45-50 kg) in at least 20 minutes.
It is recommended to start the administration slowly (for the first 50-100 mL) and to monitor the recipient carefully.
Complications, though rare, are characterised by symptoms including tachypnea, tachycardia, tremors, and colic. If this happens, reduce the speed of administration for 5-10 minutes or stop it altogether. The foal must then be subjected to a test for the evaluation of the serum IgG. If the level of IgG has remained below 8 g/L after the first administration, it is advisable to administer the second bag of plasma. The latter should not be administered before 6 hours have passed from the first infusion.
The administration occurs by infusion into the foal's jugular vein, employing a 14Gx2'' catheter previously aseptically inserted, after trichotomy and local anaesthesia at the placement site. The complete bag of plasma is then administered to the foal in at least 20 minutes, using an intravenous drip tube fitted with a filter to trap any protein aggregate.

ADVICE ON CORRECT ADMINISTRATION

Only a veterinarian must administer the medicinal product.

WITHDRAWAL PERIOD

Zero days.

SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

Store unopened in the original packaging at a temperature of -20 (±5)°C.

Do not use after the expiry date reported on the label.

The product must be used within 6 hours from thawing.

After the first opening, the product must be used immediately and not kept.

Special precautions for use in animals

It is recommended to begin the administration slowly (for the first 50-100 mL) and carefully monitor the recipient. Complications, though rare, are characterised by symptoms including tachypnea, tachycardia, tremors and colic. If it happens, further reduce the speed of administration for 5-10 minutes or stop it. If the symptoms disappear within 5 minutes, the transfusion may be continued; if instead, they occur again, stop the administration definitively. Pay attention not to cause an overload in the blood volume (infusion rate < 50 mL/min for a 50 kg foal).

Use only the product correctly stored and frozen at temperatures of -20 (±5)°C within the expiry date reported on the package.

Defrost the product in a bain-marie with a temperature not exceeding 37°C to limit flocculation and plasmatic proteins clots. Administer the drug intravenously within 6 hours from defrosting by using a drip tube fitted with a special filter to trap any protein aggregate.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

In case of accidental spillage on the skin, the medicinal product causes no harm and can be removed with water and soap.

In case of self-administration, self-injection, or accidental ingestion, immediately contact a doctor and show them the information leaflet or the label.

Usage during pregnancy and lactation

The product is not intended for use in adult horses.

The safety of the veterinary medicinal product for fertility has not been established.

Interaction with other medicinal products and other forms of interaction

The equine plasma has NO interactions with numerous classes of drugs, such as antimicrobial agents (e.g., penicillin, gentamicin, oxytetracycline), non-steroidal anti-inflammatories (e.g. flunixin meglumine), and corticosteroids (e.g. dexamethasone). Currently there is no evidence in the literature of interactions with other medicinal products administered to the foal concurrently. However, since additional studies concerning the interactions of plasma with other drugs have not yet been carried out, extreme caution is recommended in the administration of any drug together with the plasma. In any case, as there is the risk to contaminate or altering the plasma proteins, it is contraindicated to add other veterinary medicinal products to the equine plasma.

Overdose (symptoms, emergency procedures, antidotes) if necessary

The consecutive administration of 2 or more litres of plasma or a too-fast transfusion of the plasma itself can cause an overload of the blood volume with consequences for the foal's cardiopulmonary apparatus characterised by alterations in the heart and breathing rate; if these symptoms occur, immediately interrupt the administration, allowing the foal to compensate for the blood volume increase. Following the remission of symptoms, the administration can start again with a slower rate of infusion.

However, an administration of 4 litres of plasma in a suitable time-lapse was reported without side effects.

An excess of citrates (ACD) can cause muscle twitching, weakness, and heart abnormalities. If these symptoms occur, immediately stop the administration. However, the equine plasma contains a negligible amount of citrates compared to the recipient's plasma mass and studies conducted on the safety of the product in foals from 24 hours to 3 months of age, have not shown any problem on this matter.

Special precautions for disposal of the unused product or waste materials, if any

All unused or visibly damaged veterinary medicinal products, or those with an open packaging, as well as the empty bags after transfusion must be disposed of following the local regulations and given to the collecting and disposal systems for expired or unused medicinal products.

Leaflet last approved on January 2021