PlasmaLife

Frozen fresh equine plasma

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PlasmaLife

Frozen fresh equine plasma for horses.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients	Quantity
IgG	≥ 24 < 40 g/L
Total proteins	≥ 50 < 90 g/L

Excipients

ACD-A citrates (expressed as citrate ion)	< 4.73 g/L

3. PHARMACEUTICAL FORM

Preparation for intravenous use.
Equine plasma is a colloidal suspension whose color can vary from light yellow to green.

4. CLINICAL INFORMATION

4.1 Destination species

Horses.

4.2 Indications for use, specifying the destination species

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

4.3 Contraindications

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

4.4 Special warnings for each destination species

The medicinal product must only be administered by a veterinarian.

4.5 Special precautions for use

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 characterized by symptoms including tachypnea, tachycardia, tremors and colic. If this happens, further reduce the speed of administration for 5-10 minutes or stop it altogether. If the signs disappear within 5 minutes, the transfusion may continue; if instead they occur again, stop it definitively. Be careful not to cause an overload in 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 expiration date reported on the package.
Thaw the product in a water bath at temperatures not exceeding 37°C to limit flocculation and the formation of plasma protein aggregates.
Administer the drug intravenously within 6 hours of thawing using a special infusion set with a filter to trap any residues of protein aggregates.

Special precautions that must be adopted by the person administering the product to animals
In the case of accidental spillage on the skin, the drug causes no harm and can be removed with water and soap.
In the case of self-administration, self-injection or accidental ingestion, immediately contact a doctor, showing him the information leaflet or the label.

4.6 Adverse reactions (frequency and seriousness)

The risk of adverse reactions to the drug is extremely rare.
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 characterized by tachycardia, tachypnea, rash, hyperthermia, cardiac arrhythmia, muscle tremors, colic, and collapse.
In particular, the cardiac and respiratory parameters of the recipient must be monitored when the plasma administration is started. A slow infusion at the beginning of the administration allows the receiving foal to show the first signs of reaction at an early stage, so as to be able to promptly intervene to counteract the reaction itself. 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 coagulate if the product is stored in accordance with the described procedure, the risk of anaphylactic reaction is greatly reduced.
Furthermore, the use of special infusion sets for the transfusion with filters to trap any corpuscular particles present in the plasma almost completely eliminates this risk.
An excess of citrates can cause muscle twitching, weakness and heart abnormalities. However, equine plasma contains a negligible amount of these in relation to the plasma mass of the recipient and studies conducted on the safety of the product in foals from 24 hours to 3 months old have not shown any problems in this regard.

4.7 Use during pregnancy and nursing

The drug is not intended for use in adult horses.
The safety of the veterinary medicinal product for fertility has not been established.

4.8 Interaction with other veterinary 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).
There is currently no evidence in the literature of interactions with other drugs administered concurrently to the foal.
However, since additional studies have not yet been performed with regard to the interactions of plasma with other drugs, extreme caution is recommended in the administration of any drug in conjunction with the plasma. In any case, since there is the risk of contamination or alteration of the plasma proteins, it is contraindicated to add other veterinary drugs to the equine plasma.

4.9 Amounts and route of administration

The recommended dose of plasma is 20 mL per kilogram of live weight. One liter can be administered to a foal (45-50 kg) in a period of at least 20 minutes. It is recommended to start the administration slowly (for the first 50-100 mL) and carefully monitor the recipient. Complications, though rare, are characterized 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 a second bag of plasma. The latter should not be administered before 6 hours have passed after the first infusion.
The administration occurs by infusion into the foal's jugular vein, into which a 14G x 2" catheter was previously inserted, aseptically, after shaving and local anesthesia at the injection site. The entire bag of plasma should then be administered to the foal within at least 20 minutes by using a special infusion set with filter to trap any protein aggregates.

4.10 Overdose (symptoms, emergency procedures, antidotes) if necessary

The consecutive administration of 2 or more liters 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 characterized by alterations in heart rate and breathing rate; if these symptoms occur, immediately interrupt the administration, allowing the foal to compensate for the increase in blood volume. Following the remission of symptoms, the administration can be resumed with a slower rate of infusion.
The administration of up to 4 liters of plasma in a suitable period of time without causing side effects is however reported.
An excess of citrates (ACD) can cause muscle twitching, weakness and heart abnormalities. If these symptoms occur, immediately interrupt the administration. However, the equine plasma contains a negligible amount of citrates in relation to the recipient's plasma mass and studies conducted on the safety of the product in foals from 24 hours to 3 months old have not shown any problems in this regard.

4.11 Waiting time

Waiting time: zero days.

5. IMMUNOLOGICAL PROPERTIES

Therapeutic drug group: blood and related products, ATCvet code: QB05AX03

6. PHARMACEUTICAL INFORMATION

6.1 List of excipients

Acid-Citrate-Glucose (ACD) Formula A anticoagulant and preservative solution.

6.2 Incompatibility

In the absence of compatibility studies, this veterinary medicinal product should not be mixed with other veterinary medicinal products.

6.3 Period of validity

Period of validity of the veterinary medicinal product packaged for sale: 24 months.
The equine plasma should be used within 6 hours of thawing.
The product must be consumed immediately after opening and not stored.

6.4 Special precautions for storage

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

6.5 Nature and composition of the primary packaging

PVC bag containing 950 mL of product equipped with two administration tubes provided with sealed protection and fitted with a pierceable diaphragm for connection with a suitable infusion set.

6.6 Special precautions to be taken for the disposal of the unused veterinary medicinal product and of the waste materials derived from its use.

All unused or visibly deteriorated veterinary medicinal products, or those with open packaging, as well as the empty bags following transfusion must be disposed of in accordance with local regulations.

7. HOLDER OF THE MARKETING AUTHORIZATION

Name: IL CEPPO S.a.s.
Address: Via di Monteresi, 3-53035 Monteriggioni (SI)
Country: Italy
Telephone: 0577-318683
Fax: 0577-574624
E-mail: info@plasmalife.it

8. NUMBER OF THE MARKETING AUTHORIZATION

950 mL PVC bag marketing authorization no.: 104114018

9. DATE OF THE FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION

Date of first authorization: January 2011

10. DATE OF REVISION OF THE TEXT

November 2013

11. PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

12. DISPENSING PROCEDURES

To be sold only upon presentation of a veterinary prescription in triplicate, not repeatable.
The medicinal product must only be administered by a veterinarian.