PRECISEPRP EQUINE- equine leucoreduced allogeneic pooled freeze-dried platelet-rich plasma injection, powder, for suspension
VetStem, Inc.

Caution

Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

Description:

PrecisePRP™ Equine is a leucoreduced allogeneic, pooled freeze-dried, platelet-rich plasma product from up to 18 equine donors. The biological source material for this product is in-date, apheresis-derived equine platelet concentrates leucoreduced to less than 1500 white blood cells per µL and apheresis-derived frozen plasma. All horses are blood type AaCa positive and negative for plasma antibodies (A,C,K,P,Q,U, and D) . Donors are from a closed herd compliant with USDA regulations for production of licensed biologics. Donors are selected and evaluated for infectious disease in accordance with FDA CVM Guidance #254. Supplied in a 50 mL glass vial, this product is a sterile, nonpyrogenic white-to-tan powder. Once rehydrated with 8 mL of sterile water for injection, this product is a gold translucent fluid with 4.0 x 109 platelets per vial and less than 1500 white blood cells per µL.

Indication:

PrecisePRP™ Equine is intended to provide a species-specific source of concentrated platelets in plasma for intra-articular administration.

Dosage and Administration:

PrecisePRP™ Equine is for intra-articular administration only. One vial provides 8 mL of leucoreduced allogeneic pooled freeze-dried platelet-rich plasma with a total of approximately 4 x 109 equine platelets per vial and less than 1500 white blood cells per µL. Do not mix this product with other products or solutions. Use this product according to the instructions below.
Rehydration instructions (Perform Aseptically):
• Draw 8 milliliters of sterile water into a sterile syringe and needle.
• Apply the supplied vented administration clave to the PrecisePRP™ Equine vial and firmly seat it on the crimped seal.
• Disengage the needle and, using sterile technique, attach the syringe to the clave hub.
• Slowly add the sterile water down the side of the vial lumen to avoid foaming and immerse the cake in the rehydrating fluid.
• Gently mix the fluid and the lyophilized powder by swirling the vial to rehydrate.
• Draw into a syringe using the bidirectional clave.
• Engage a needle greater than or equal to 22 gauge for administration.
• Store at room temperature (18-25℃) until administration for not more than four (4) hours.

• Discard the excess product.

Dosage is lesion dependent and determined by the practitioner at the time of use. Each microliter of PrecisePRP™ Equine contains 500,000 +/- 100,000 platelets and less than 1500 white blood cells. The dose given may be adjusted based on the size of the joint to be injected. As a general rule, the dosage per joint should be 2-4 mL

Contraindications:

Do not use in horses with known hypersensitivity to PrecisePRP™ Equine.

Warnings:

For use in horses only. Not for use in humans. Keep out of reach of children.
Rehydrated PrecisePRP™ Equine should be used within 4 hours of rehydration.

Precautions:

PrecisePRP™ Equine has only been tested in mature adult horses.
PrecisePRP™ Equine has not been evaluated in breeding, pregnant, or lactating horses.
PrecisePRP™ Equine is not intended for intravenous administration.
PrecisePRP™ Equine has not been tested in donkeys or mules.

Adverse Reactions:

PrecisePRP Equine is made using platelets and plasma from up to 18 Equine donors and, as with all blood products, has a risk of infectious disease. Donor maintenance includes routine screening for pathogens by PCR and ELISA testing.
In a placebo-controlled study of 12 adult horses, PrecisePRP Equine was tested at the label dose of 4 mL per joint in two consecutive joint injections two weeks apart. The horses were monitored for treatment-related effects on gait, daily health observations, temperature, pulse, respiration, clinical pathology, injection sites, veterinary physical exams and the reported adverse events by treatment group are reported in Table 1.

Table 1. Adverse events reported in the placebo-controlled safety study

Adverse Event	**PrecisePRP™ Equine (N=6)**	**Saline Placebo (N=6)**
Mild transient lameness post-injection	1	4
Colic	0	1

The mild lameness reported resolved within 1 day in the PrecisePRP group and within 1-2 days in the Placebo group.

Published safety data exists for both canine and equine allogeneic platelet-rich plasma. Clinical case reports, systemic literature reviews, preclinical safety analysis, and comparative studies with autologous platelet-rich plasma and mesenchymal stem cells are available for the horse and dog. In the safety evaluation of equine platelet-rich

plasma published by Garbin[1], a pooled allogeneic freeze-dried platelet-rich plasma was evaluated with autologous frozen products for safety and found to be statistically unremarkable from autologous products relating to inflammation and lameness post injection. In an Italian clinical trial in canine patients, no adverse events associated with immunogenicity were noted utilizing a pooled allogeneic platelet-rich plasma[2].
Report any suspected adverse reactions associated with the use of PrecisePRP Equine to VetStem Customer Service by calling 858-748-2004. For additional information about adverse drug experience reporting animal drugs, contact FDA at 1-888-FDA-VETS or visit http://www.fda.gov/animalveterinary/safetyhealth.

Information for Horse Owners:

Owners of patients should be made aware of the use of allogeneic blood products and their possible side effects. Adverse reactions may include joint pain for several days following injection, transient inflammation and swelling in the injected joint, and joint infections and transmission of disease agents from donor animals.

Clinical Pharmacology:

Platelet-rich plasma has been studied in multiple species with varying use profiles. A thorough review of the literature yielded over 30 references in support of platelet-rich plasma and its use as a topical, intraarticular and/or intralesional therapy published since 2008. Meta-analysis in human clinical trials as well as multiple study reviews in canine and equine suggest that the most common concern for platelet-rich plasma effectiveness is associated with a lack of uniformity and standardization[3, 4]. Important components of platelet-rich plasma have been debated; however, total platelet dose, growth factor content, and leucocyte count appear to be common factors for most authors when relating in vitro characterization and effectiveness outcomes[5]. Review of the veterinary literature was used to support both potential indications as well as dose and administration.
Platelets are provided to supply the growth factors and cytokines located in the alpha granules. After administration, the growth factors and cytokines are released into the area of injection and provide anti-inflammatory cytokines and repair signaling. Platelets also release factors that attract mesenchymal stem cells, leucocytes, and other mononuclear immune cells to assist in the repair process. It has been reported that platelet-rich plasma injected reduces pain signaling.
Recently, the discussion of platelet phenotypes and their relationships to platelet function, circulation, and membrane characteristic have led to the exploration of new methods for platelet concentrate storage, including storage at 4-8°C. Current published uses of platelet-rich plasma in the canine and equine support that it can be used intra-articularly, intralesionally, or topically and should be activated to allow the release of dense and alpha granules. Cold-stored platelets have been characterized as moderately activated as compared to room temperature-stored platelets. Recent in vitro characterization of the cold-stored platelets supports that their phenotype is most consistent with the desired function of platelet-rich plasma[6]. Manipulating the storage parameter for platelet concentrates prior to pooling and lyophilization allows platelet lyophilization without cryopreservatives (VetStem pilot data, 2022).

References:

1. Garbin, L.C., et al., A safety evaluation of allogeneic freeze-dried platelet-rich plasma or conditioned serum compared to autologous frozen products equivalents in equine healthy joints. BMC Vet Res, 2022. 18(1): p. 141.
2. Catarino, J., et al., Treatment of canine osteoarthritis with allogeneic platelet-rich plasma: review of five cases. Open Vet J, 2020. 10(2): p. 226-231.
3. Everts, P.A., et al., Modifying Orthobiological PRP Therapies Are Imperative for the Advancement of Treatment Outcomes in Musculoskeletal Pathologies. Biomedicines, 2022. 10(11).
4. Garbin LC, et al., (2021), A Critical Overview of the Use of Platelet-Rich Plasma in Equine Medicine Over the Last Decade. Front. Vet. Sci. 8:641818.
5. McCarrel, T. and L. Fortier, Temporal growth factor release from platelet-rich plasma, trehalose lyophilized platelets, and bone marrow aspirate and their effect on tendon and ligament gene expression. J Orthop Res, 2009. 27(8): p. 1033-42.
6. Zhao, H.Q., et al., Cold-stored platelets are effective in an in vitro model of massive transfusion protocol assessed by rotational thromboelastometry. Transfusion, 2022. 62 Suppl 1: p. S53-S62.

PrecisePRP™ is a trademark of VetStem, Inc.
 2024 VetStem, Inc.

Patent Pending
Revised 30Jan2024
6235-0003-002

7.576"

PRECISE PRP™ Equine

/Equine Leucoreduced Allogeneic Pooled Freeze-Dried Platelet-Rich Plasma

VetStem, Inc.
Poway, CA 92064
858-748-2004
www.VetStem.com

Patent Pending

Made in the USA

FDA VMF6494
FDA-Reviewed ACTP

4210-0002-002

Storage: Store lyophilized and rehydrated product at room temperature (18-25°C). Use PrecisePRP™ Equine within 4 hours of rehydration.

Use Precautions: FOR USE IN HORSES ONLY. Not for use in humans. Keep out of reach of children. This product has only been tested in mature adult horses.

Not for intravenous use
Single patient use

Notify VetStem immediately of suspected adverse reaction at 858-748-2004 or contact FDA at 1-888-FDA-VETS.

PRECISE PRP™ Equine

/Equine Leucoreduced Allo Pooled Freeze-Dried Platelet-Rich Plasma

Caution: Federal law restri this drug to use by or on the order of a licensed veterina

VetStem

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PRECISEPRP™ Equine

Equine Leucoreduced Allogeneic Pooled Freeze-Dried Platelet-Rich Plasma

4 x 10^9 platelets per 8 mL
< 1500 white blood cells per µL

Not for intravenous use
For use in horses only
Single patient use

Rx Only

VetStem, Inc.
Poway, CA 92064
858-748-2004

FDA VMF6494
FDA-Reviewed ACTP
4210-0001-002

Dosing: For intra-articular use in horses only. See prescribing information insert for dosing instructions.
Storage: Store lyophilized product at room temperature (18-25°C).
Rehydration: Apply the administration clave and add 8 mL of sterile water. Mix by swirling. Do not foam. Use PrecisePRP™ Equine within 4 hours of rehydration.

Patent Pending

Made in the USA

Lot No.:

Exp. Date:

PRECISEPRP EQUINE

equine leucoreduced allogeneic pooled freeze-dried platelet-rich plasma injection, powder, for suspension

Product Information

Product Type		**Item Code (Source)**	NDC:86198-111
Route of Administration	INTRA-ARTICULAR		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
EQUINE ALLOGENEIC FREEZE-DRIED PLATELET-RICH PLASMA (UNII: 65DAW2DYZ6) (EQUINE ALLOGENEIC FREEZE-DRIED PLATELET-RICH PLASMA - UNII:65DAW2DYZ6)	EQUINE ALLOGENEIC FREEZE-DRIED PLATELET-RICH PLASMA	400000000 in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:86198-111-50	1 in 1 CARTON		
1		50 mL in 1 VIAL		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/01/2024	

Labeler - VetStem, Inc. (118746255)

Registrant - VetStem, Inc. (118746255)

Establishment

Name	Address	ID/FEI	Business Operations
VetStem, Inc.		118746255	repack

Establishment

Name	Address	ID/FEI	Business Operations
Quality Bioresources, Inc.		858704802	manufacture

Revised: 5/2024

VetStem, Inc.