SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

RenuTend suspension for injection for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 1 ml contains:

Active substance:
Tenogenic primed equine allogeneic peripheral blood-derived mesenchymal stem cells (tpMSCs): 2.0–3.5 x 10^6

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.
Clear, colourless suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Horses

4.2 Indications for use, specifying the target species

To restore fibre alignment in horses with superficial digital flexor tendon or suspensory ligament fibre disruption

4.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not administer simultaneously with any other intra-lesional veterinary medicinal product

4.4 Special warnings for each target species

The veterinary medicinal product has been demonstrated to be efficacious in horses with first time overstrain lesions in the superficial digital flexor tendon of the front leg, or the suspensory ligament in the back or front leg. Efficacy data are not available regarding treatment of other tendons and ligaments. Treatment of traumatic injuries with lacerations or completely ruptured tendons has not been evaluated. This veterinary medicinal product is not intended for treatment of such injuries.

The efficacy of the veterinary medicinal product was demonstrated in a pivotal field trial with horses working at training level or competition level within the disciplines dressage or show jumping, before tendon or ligament injury occurred. By day 112 post-treatment, 65% of horses treated with this product during the pivotal field trial had achieved greater than 75% fibre alignment within the affected soft tissues.

A standard program of box rest and slowly increasing exercise regimen under veterinary guidance is required as part of the rehabilitation of tendon and ligament injuries. The program should be adapted based on serial ultrasonographic monitoring and clinical signs such as lameness, heat and swelling.

The efficacy and safety of the veterinary medicinal product were demonstrated in a pivotal field trial after single administration of the veterinary medicinal product and concurrent single systemic administration of an NSAID (ketoprofen or meloxicam). According to the benefit-risk assessment of the responsible veterinarian of the individual case a single dose systemic NSAID may be administered on the day of intra-lesional injection.

4.5 Special precautions for use

Special precautions for use in animals

A correct foot balance is critical in the management of superficial digital flexor tendon or suspensory ligament lesions.

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

When the veterinary medicinal product is stored in liquid nitrogen, direct exposure to liquid nitrogen or cold nitrogen vapours can cause extensive tissue damage or burns. When liquid nitrogen vaporises, it can expand to 700-times its volume which may create an explosion hazard in unvented cryovials. Liquid nitrogen containers should be handled by properly trained personnel only. The handling of liquid nitrogen should take place in a well-ventilated area. Before withdrawing the vials from the liquid nitrogen canister, protective equipment consisting of gloves, long sleeves and a facemask or goggles should be worn.

There is only limited data available to support the human safety of this product. In particular, women of childbearing age and people with compromised immune systems should take care to avoid contact with the product. It is recommended to wear impermeable gloves at all times whilst handling and administering the product. Wash any spills off exposed skin, eyes, or mucous membranes immediately.

Take care not to accidentally self-administer this product. In case of accidental self-injection, this veterinary medicinal product can cause pain, local inflammatory reactions and swelling at the site of injection, which may persist for several weeks. Transient fever may also occur. Seek medical advice immediately and provide the package leaflet or label to the physician.

4.6 Adverse reactions (frequency and seriousness)

Mild injection site reactions, such as increased heat, pain at palpation, limb swelling and increased limb circumference occurred very commonly during the first 10 days after administration.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.
Use only according to the benefit-risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

Do not administer simultaneously with any other intra-lesional veterinary medicinal product.'

4.9 Amounts to be administered and administration route

Route of administration:
Intra-lesional use.

Dosage*:*
A single intra-lesional injection of 1 ml per animal on one occasion.

Preparation of the suspension for injection:
The veterinary medicinal product must be administered intra-lesionally by a licensed veterinarian taking special precautions to ensure sterility of the injection process. The veterinary medicinal product should be handled and injected using sterile techniques and in a clean environment.

The veterinary medicinal product is required to be administered immediately after thawing in order to maintain cell viability.

Using appropriate gloves, remove the vial from the freezer/liquid nitrogen and thaw immediately at 25 °C–37 °C, e.g. in a water bath, until the content is completely thawed (approximately 5 minutes).

If any cell clusters are visible after thawing, gently invert the vial until the suspension is clear and colourless.

Remove the cap of the vial and aspirate the suspension into a sterile syringe for injection.

Administer using a needle with a diameter greater than or equal to 22G in order to prevent cell damage.

Administer intra-lesionally under ultrasound guidance with chemical or physical restraint as needed according to good veterinary practice to facilitate a safe intra-lesional injection. After insertion of the needle into the tendon or ligament, redirect the needle, if necessary, until the lesion is reached. Slowly inject the suspension. In case of a larger lesion the needle can be slowly retracted during injection to facilitate dispersion of the cells throughout the lesion.

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

No data available.

4.11 Withdrawal period(s)

Meat and Offal: zero days
Milk: zero hours

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Musculo-skeletal system, other drugs for disorders of the musculo-skeletal system, equine stem cells
ATC vet code: QM09AX90

5.1 Pharmacodynamic properties

This veterinary medicinal product contains tenogenic primed equine allogeneic peripheral blood-derived mesenchymal stem cells (tpMSCs). The beneficial effects of tpMSCs were observed in an experimental tendon injury model in horses. After tpMSC administration the treated horses showed improved ultrasound echogenicity and fibre alignment scores, higher percentages of intact and fully aligned tendon fascicles,higher collagen type I to type III ratio and lower smooth muscle actin levels than horses treated with a saline control.

5.2 Pharmacokinetic particulars

After injection of the veterinary medicinal product, the tpMSCs do not migrate or distribute from the treated tendon to surrounding tissues or the draining lymph node.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dulbecco’s Modified Eagle Medium Low Glucose
Dimethyl sulfoxide

6.2 Major incompatibilities

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

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after thawing according to directions: Use immediately.

6.4. Special precautions for storage

Store and transport frozen (-90 °C to -70 °C) or in liquid nitrogen.

6.5 Nature and composition of immediate packaging

Cyclo-olefin co-polymer (COC) vial with a thermoplastic elastomer (TPE) stopper and a high-density polyethylene (HDPE) cap containing a single dose of stem cell suspension.

Each pack (polycarbonate container or cardboard box) contains a single dose of the veterinary medicinal product: one vial (1 ml) of stem cell suspension.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

8. MARKETING AUTHORISATION NUMBER

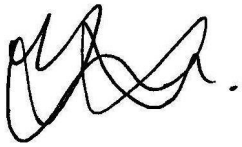
Vm 04491/5064

9. DATE OF FIRST AUTHORISATION

05 May 2022

10. DATE OF REVISION OF THE TEXT

May 2022



Approved: 19 May 2022