SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Arti-Cell Forte suspension for injection for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 ml dose - contains:

Active substance (1 ml):
Chondrogenic induced equine allogeneic peripheral blood-derived mesenchymal stem cells (1 ml)
$1.4–2.5×10^6$

Excipients (1ml):
Equine allogeneic plasma (EAP) 1 ml

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.
Chondrogenic induced equine allogeneic peripheral blood-derived mesenchymal stem cell suspension: clear colourless suspension.
Equine allogeneic plasma suspension (diluent): clear yellow suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Horses

4.2 Indications for use, specifying the target species

Reduction of mild to moderate recurrent lameness associated with non-septic joint inflammation in horses.

4.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings for each target species

The product has been demonstrated to be efficacious in horses showing mild to moderate lameness in the fetlock joint.

Efficacy data are not available regarding treatment of other joints.

The efficacy of the product was demonstrated in a pivotal field trial after single administration of the product and concurrent single systemic administration of an NSAID. 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 intraarticular injection.

4.5 Special precautions for use

Special precautions for use in animals
In order to avoid thrombosis in small vessels when administering intraarticular injections the correct placement of the needle is critical.

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

In case of accidental self-injection this product can cause pain, local inflammatory reactions and swelling at the site of injection which may persist for several weeks and possibly cause fever, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

Mild increases in lameness and injection site reactions, such as mild to moderate increases in joint swelling and mild increases in temperature at the injection sites, occurred very commonly in the first week after use of the product. In the pivotal clinical field study a single systemic administration of an NSAID was given concurrently to treatment with Arti-Cell Forte.

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 accordingly to the benefit-risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

No data available.
Do not administer simultaneously with any other intraarticular veterinary medicinal product.

4.9 Amounts to be administered and administration route

Route of administration:
Intraarticular use.

Dosage*:*
A single intraarticular injection of 1 dose (2 ml) per animal.

Preparation of the suspension for injection:
The veterinary product must be administered intraarticularly by a veterinary surgeon taking special precautions to ensure sterility of the injection process. The product must be manipulated and injected using sterile techniques and in a clean environment.

The product needs to be administered immediately after thawing to prevent significant cell death.

Using appropriate gloves, remove the two vials (one vial of cells (1 ml) and one vial of EAP (1ml)) from the freezer/liquid nitrogen and thaw immediately at 25 °C – 37 °C, e.g. in a water bath, until the contents in each are completely thawed (approximately 5 minutes).

If any cell clusters are visible in either of the vials after thawing, gently shake the vial concerned until the suspension is clear and colourless (stem cell suspension) or clear and yellow (equine allogeneic plasma suspension: the diluent).

Remove the cap of the vial that thawed first and aspirate the suspension in a syringe, then remove the cap of the other (thawed) vial and aspirate the suspension in the same syringe. Then mix both the suspensions in the same syringe to produce one dose of the product (2 ml).

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

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

No data available.

4.11 Withdrawal period(s)

Zero days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Other drugs for disorders of the musculo-skeletal system
ATCvet code: QM09AX90

5.1 Pharmacodynamic properties

This product contains chondrogenic induced equine mesenchymal stem cells and equine allogeneic plasma (EAP). The addition of the EAP to the stem cells after thawing and just before injection of the product increases the viability of the stem cells.

The chondrogenic induction of the mesenchymal stem cells aims to activate chondroprotective mechanisms, such as the production of extracellular matrix. In an experimental model of osteoarthritis in horses these effects were reflected through parameters related to cartilage turnover.

5.2 Pharmacokinetic particulars

After injection of the product the stem cells do not migrate or distribute from the treated joint and synovia to tissues surrounding the synovial space.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Active substance (stem cells) vial:
Dimethyl sulfoxide
Dulbecco's Modified Eagle Medium Low Glucose

Diluent (EAP) vial:
Equine allogeneic plasma

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: 3 years.
Shelf life after reconstitution 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

Chondrogenic induced mesenchymal stem cell suspension:
Cyclo-olefin co-polymer (COC) vial with a thermoplastic elastomer (TPE) stopper and a high-density polyethylene (HDPE) cap.

Equine allogeneic plasma suspension:
Cyclo-olefin co-polymer (COC) vial with a thermoplastic elastomer (TPE) stopper and a high-density polyethylene (HDPE) cap.

Each pack (polycarbonate container) contains a single dose of the product: one vial of stem cell suspension and one vial of EAP 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 04491/5062

9. DATE OF FIRST AUTHORISATION

29 March 2019

10. DATE OF REVISION OF THE TEXT

October 2023

Approved: 06 October 2023