ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Polycarbonate container

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Arti-Cell Forte suspension for injection for horses

2. STATEMENT OF ACTIVE SUBSTANCES

1.4–2.5×10^6 chondrogenic induced equine allogeneic peripheral blood-derived mesenchymal stem cells

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

One vial (1 ml) of stem cells and one vial (1 ml) of equine allogeneic plasma.

5. TARGET SPECIES

Horses

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Intraarticular use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once reconstituted use immediately.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
Germany

16. MARKETING AUTHORISATION NUMBER(S)

Vm 04491/5062

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Arti-Cell Forte Suspension for injection

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

$1.4–2.5×10^6$ cells

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 ml

4. ROUTE(S) OF ADMINISTRATION

Intraarticular use

5. WITHDRAWAL PERIOD(S)

Withdrawal period: zero days

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Once reconstituted use immediately.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Diluent for Arti-Cell Forte

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 ml

4. ROUTE(S) OF ADMINISTRATION

Intraarticular use

5. WITHDRAWAL PERIOD(S)

Withdrawal period: zero days

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Once reconstituted use immediately.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Arti-Cell Forte suspension for injection for horses

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

Manufacturer responsible for batch release:
Boehringer Ingelheim
Veterinary Medicine Belgium NV
Noorwegenstraat 4
9940 Evergem
BELGIUM

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Arti-Cell Forte suspension for injection for horses
Chondrogenic induced equine allogeneic peripheral blood-derived mesenchymal stem cells

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each dose (2 ml) contains:

Active substance (1 ml):

$1.4–2.5\times10^{6}$ Chondrogenic induced equine allogeneic peripheral blood-derived mesenchymal stem cells (1 ml)
Colourless and clear suspension.

Excipients (1 ml):
Equine allogeneic plasma (1 ml)
Yellow and clear suspension.

4. INDICATION(S)

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

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

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.

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).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Horses

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For intraarticular use.

Dosage:
Single administration of 1 dose (equivalent to 2 ml) per animal

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store and transport frozen (⁻90 ° to ⁻70 °C) or in liquid nitrogen.
Do not use this veterinary medicinal product after the expiry date which is stated on the labels. The expiry date refers to the last day of that month.
Shelf life after preparation of the suspension for injection according to directions: use immediately

12. SPECIAL WARNING(S)

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.

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.

Pregnancy and lactation:
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.

Interaction with other medicinal products and other forms of interaction:
No data available.
Do not administer simultaneously with any other intraarticular veterinary medicinal product.

Overdose:
No data available

Major incompatibilities:
In the absence of incompatibility studies, this veterinary product must not be mixed with other veterinary medicinal products

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2022

15. OTHER INFORMATION

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

Approved: