ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton Box 10 x 1 Dose , 2 x 1 Dose, 1 x 1 Dose

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equip Artervac emulsion for injection for horses and ponies

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 1 ml contains:

Active substance
Inactivated Equine Arteritis Virus, Bucyrus strain 1.0-1.8 RP

3. PHARMACEUTICAL FORM

Emulsion for injection.

4. PACKAGE SIZE

1x 1 single-dose syringe.
2x 1 single-dose syringe.
10x 1 single-dose syringe.

5. TARGET SPECIES

Horses and ponies from the age of 9 months.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before 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}

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Protect from light.
Do not freeze.

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

Disposal: read package leaflet.

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

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

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER

Vm 42058/4059

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Syringe label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equip Artervac emulsion for injection for horses and ponies

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Inactivated Equine Arteritis Virus

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

1 ml

4. ROUTE(S) OF ADMINISTRATION

IM

5. WITHDRAWAL PERIOD(S)

Withdrawal period(s): Zero days

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Equip Artervac emulsion for injection for horses and ponies

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

Marketing authorisation holder:
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

Manufacturer responsible for batch release:
Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-La-Neuve
BELGIUM

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equip Artervac emulsion for injection for horses and ponies

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

Each dose of 1 ml contains:

Active substance

Inactivated Equine Arteritis Virus, Bucyrus strain	1.0 – 1.8 RP*

* Relative Potency compared to a reference vaccine

Adjuvant

Squalane	0.2% (v/v)
Pluronic L-121	0.1% (v/v)
Polysorbate 80	0.016% (v/v)

Red/rust coloured liquid

4. INDICATION(S)

For the active immunisation of horses and ponies against equine arteritis in order to reduce clinical signs and shedding of virus in nasal secretion after infection.

Onset of immunity: 3 weeks post primary vaccination
Duration of immunity: 6 months

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

Minor transient (1 to 5 days) increase in body temperature (<40°C) and transient local reactions (for usually 2 to 3 days) may be very commonly observed in vaccinated horses. The swellings are usually less than 4 cm in diameter, but in one horse a swelling of 20 cm lasting for 5 days was recorded. All swellings resolved.
Systemic reactions which includes depression and ocular and nasal discharge may be commonly observed. Urticaria and oedema of legs, abdomen or scrotum may be rarely observed.

In the event of an allergic or anaphylactic reaction, adrenaline should be administered intramuscularly.

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 serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Horses and ponies from the age of 9 months.

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

1 ml dose per horse to be administered by intramuscular injection.

Primary course:
A single dose should be administered two times with an interval of 3-6 weeks from an age of nine months onwards.

Booster vaccinations are recommended every 6 months.

9. ADVICE ON CORRECT ADMINISTRATION

Shake well before use.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store and transport refrigerated (2 °C – 8 °C).
Protect from light.
Do not freeze.

Do not use this veterinairy medicinal product after the expiry date which is stated on the carton and the syringe after EXP.

12. SPECIAL WARNING(S)

Special warnings for use in animals:
Vaccinate healthy animals only.
Vaccination does not prevent infection.
Vaccination does not have an effect on the shedding of EAV by previously infected carrier stallions.
The effect of the vaccine on the fertility of breeding stallions has not been investigated.
Under some national legislation EVA is a notifiable disease (UK). Please refer to the national product literature for recommendations on vaccination to comply with this legislation.

UK Only:
Equine viral arteritis (EVA) is a notifiable disease in the UK. Vaccinated horses will become seropositive and therefore it is recommended that they are blood tested prior to primary vaccination to demonstrate that they were previously seronegative. Details of blood testing and vaccination schedule should be recorded in the horse passport.

Special precautions for use in animals:
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation:
Do not use in pregnant mares.

Interaction with other medicinal products and other forms of interaction:
Animals that have received immunosuppressive drugs (e.g. glucocorticoids) should not be vaccinated until an interval of at least 4 weeks has elapsed.
No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

Overdose (symptoms, emergency procedures, antidotes):
Administration of a twofold overdose has no influence on the systemic reactions to vaccination as described in section "Adverse Reactions". Local swellings (< 4 cm in size) were observed in 80% of horses administered two doses of vaccine, these swellings were observed for one day only.

Incompatibilities:
Do not mix with any other veterinary medicinal product.

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

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

March 2020

15. OTHER INFORMATION

Pharmacotherapeutic group: Inactivated viral vaccines.
ATCvet code: QI05AA07.

For animal treatment only.

Pack sizes:
Syringes are supplied in a cardboard box of 1, 2 and 10 units
Not all pack sizes may be marketed.

Legal Category:

For animal treatment only – to be supplied only on veterinary prescription.

Marketing Authorisation No.:
42058/4059

Approved 08 April 2020