1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equip Artervac emulsion for injection for horses and ponies.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml dose contains:

Active substance:
Equine arteritis virus, strain Bucyrus, inactivated 1.0 – 1.8 RP*

*Relative potency compared to a reference vaccine

Adjuvants:

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

Excipients:

Qualitative composition of excipients and other constituents
Eagles Hepes (0.05 % LAH) Medium
Phosphate Buffered Saline

Red/rust coloured emulsion.

3. CLINICAL INFORMATION

3.1 Target species

Horses and ponies.

3.2 Indications for use for each target species

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
Duration of immunity: 6 months

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.
Vaccination does not prevent infection.

3.5 Special precautions for use

Special precautions for safe use in the target species:
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.

Special precautions for the protection of the environment:
Not applicable.

Other precautions:
Vaccination does not have an effect on the shedding of EAV by previously infected carrier stallions. The effect of the veterinary medicinal product on the fertility of breeding stallions has not been investigated.

3.6 Adverse events

Horses and ponies:

Very common (>1 animal / 10 animals treated):	Injection site swelling[1] Elevated temperature[2]
Common (1 to 10 animals / 100 animals treated):	Ocular discharge Nasal discharge Depression
Rare (1 to 10 animals / 10,000 animals treated):	Allergic reaction[3], Anaphylactic-type reaction[3], Localised allergic oedema (oedema of the legs, abdominal oedema, scrotal oedema)[3], Urticaria[3]

[1]Transient, usually lasting for 2 to 3 days. 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.
[2]Minor transient (1 to 5 days) increase in body temperature (<40°C).
[3]If such reactions occur, adrenaline should be administered intramuscularly.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Do not use (during the whole or part of the pregnancy).

3.8 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.

3.9 Administration routes and dosage

Shake well before use.

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 vaccination:
Booster vaccinations are recommended every 6 months.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Administration of a twofold overdose has no influence on the systemic reactions to vaccination as described in section 3.6 “Adverse events”. 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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

The import, sale, supply and/or use of this vaccine is restricted or prohibited in Ireland pursuant to national animal health policy. Any person intending to import, sell, supply and/or use this vaccine must consult the Department of Agriculture on the current vaccination policies prior to import, sale, supply and/or use.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI05AA07

The vaccine induces an active immunity against equine arteritis virus, strain Bucyrus in horses and ponies.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Sterile single-use Type I glass syringes containing one dose each and closed with bromobutyl rubber tips.
Syringes are supplied in a cardboard box of 1, 2 and 10 units.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10387/027/001

8. DATE OF FIRST AUTHORISATION

21 June 2013

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

03 July 2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).