SUMMARY OF PRODUCT CHARACTERISTICS

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

3. PHARMACEUTICAL FORM

Emulsion for injection.
Red/rust coloured emulsion.

4. CLINICAL PARTICULARS

4.1 Target species

Horses and ponies.

4.2 Indications for use, specifying the 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

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.
Vaccination does not prevent infection.

4.5 Special precautions for use

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.

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.

4.6 Adverse reactions (frequency and seriousness)

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 the national competent authority via the national reporting system. See also section 16 of the package leaflet for contact details.

4.7 Use during pregnancy, lactation or lay

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

4.8 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.

4.9 Amount(s) to be administered and administration route

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.

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

Administration of a twofold overdose has no influence on the systemic reactions to vaccination as described in section 4.6 “Adverse Reactions (frequency and seriousness)”. 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.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Inactivated viral vaccines.

ATCvet code: QI05AA07

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Eagles Hepes (0.05 % LAH) Medium
Phosphate Buffered Saline

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

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

6.4 Special precautions for storage

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

6.5 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.

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

Medicines should not be disposed of via wastewater.

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

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 42058/5147

9. DATE OF FIRST AUTHORISATION

17 June 2005

10. DATE OF REVISION OF THE TEXT

July 2024

11. PROHIBITION OF SALE, SUPPLY AND/OR USE

Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must first consult the relevant competent authority on the current vaccination policies, as these activities may be prohibited in a country on the whole or part of its territory pursuant to national legislation.

12. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk.

Gavin Hall

Approved: 04 March 2025