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 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)

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 from the age of 9 months.

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 post primary vaccination
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.
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.

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.

4.6 Adverse reactions (frequency and seriousness)

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).

4.7 Use during pregnancy, lactation or lay

Do not use in pregnant mares.

4.8 Interaction with other medicinal products and other forms of interactions

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 Amounts 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 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 ''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.

4.11 Withdrawal period(s)

Zero days.

5 PHARMACOLOGICAL or 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
Pluronic L-121
Squalane
Polysorbate 80

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 products or waste materials derived from the use of such products

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 Belgium S.A.
2nd Floor, Building 10
Cherrywood Business Park, Loughlinstown
Co Dublin
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10387/027/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 07 July 2005
Date of last renewal: 23 March 2010

10 DATE OF REVISION OF THE TEXT

March 2020

PROHIBITION OF SALE, SUPPLY AND/OR USE

The import, sale, supply and/or use of Artervac Emulsion for Injection is restricted or prohibited in Ireland pursuant to national animal health policy.

Any person intending to import, sell supply and/or use Artervac Emulsion for Injection must consult the Department of Agriculture on the current vaccination policies prior to import, sale, supply and/or use.