1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BioEquin EHV emulsion for injection for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml dose contains:
Active substance:
Equine herpesvirus 1, strain Bio 82, inactivated min. 2.1 $\log_{10}$ VNI[1]

[1]Virus neutralization index determined in serum of hamsters

Adjuvants:
Montanide ISA 35 VG 0.25 ml

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Thiomersal	0.1 mg
Sodium chloride	
Potassium chloride	
Potassium dihydrogen phosphate	
Disodium hydrogen phosphate dodecahydrate	
Water for injection	
Sodium hydroxide (for pH adjustment)	

The vaccine is an oily liquid, creamy white, yellowish or pale pink colour, with easily shakeable sediment.

3. CLINICAL INFORMATION

3.1 Target species

Horses.

3.2 Indications for use for each target species

For active immunization of horses to reduce clinical signs and to reduce virus excretion during respiratory disease caused by equine herpesvirus 1 (EHV-1) infections.

Onset of immunity: 2 weeks after the second vaccine injection
Duration of immunity has only been demonstrated after the administration of three vaccine injections (see section 3.9): 6 months after the 3rd vaccine injection.

For active immunisation of pregnant mares to reduce the occurence of abortions caused by equine herpesvirus 1 (EHV-1) infections.

Onset immunity: 3 weeks after the 3rd vaccine injection during gestation
Duration of immunity: until the end of pregnancy.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

In order to reduce the infection pressure, all horses on the same premises should be vaccinated. Before transfer of horses to other herds or stables, or before races, vaccination should be performed allowing for at least 14 days for onset of immunity. Before inclusion in a herd, horses should be vaccinated and kept in quarantine until onset of immunity is reached. Sick horses with signs of a respiratory disease should be isolated from healthy animals.

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 label to the physician.

To the user:
This veterinary medicinal product contains an oily adjuvant based on non-mineral oil. Accidental injection/self-injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given. If you are accidentally injected with this veterinary medicinal product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This veterinary medicinal product contains an oily adjuvant based on non-mineral oil. Even if small amounts have been injected, accidental injection with this veterinary medicinal product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Horses:

Very common (>1 animal / 10 animals treated):	Hyperthermia[1]
Rare	Injection site reaction[2]

(1 to 10 animals / 10 000 animals treated):	
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Anaphylaxis[3]

[1] Temporary, max. 40°C for 4 days.
[2] Up to 5x10 cm in diameter for a maximum 5 days.
[3] Symptomatic treatment should be provided.

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 the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Can be used during pregnancy.
The safety of the veterinary medicinal product has not been established during lactation.

3.8 Interaction with other medicinal products and other forms of interaction

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

Intramuscular use.
Administer the vaccine dose (1 ml) by deep intramuscular injection.
Before use, allow the vaccine to reach a temperature of 15-25 °C.
Shake well before use.

Vaccination schedule:

Primary vaccination:
The basic immunisation schedule consists of three vaccine injections: the first injection from the age of 6 months; the second injection 4 weeks later, and the third injection is administered 3 months after the second dose.

Revaccination:
Administer one dose of vaccine 6 months after completion of the primary vaccination schedule, and thereafter every 6 months.

Vaccination of pregnant mares:
To reduce the incidence of abortions, administer one dose of the vaccine in the second month after mating, one dose in the fifth or sixth month of pregnancy, and one dose in the ninth month of pregnancy. The three dose vaccination scheme should be repeated for subsequent pregnancies.

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

Not applicable.

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

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI05AA05

For active immunization against equine herpesvirus.

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: 18 months.
Shelf life after first opening the immediate packaging: 10 hours.

5.3 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).
Protect from light.

5.4 Nature and composition of immediate packaging

The vaccine is filled in glass vials of hydrolytic class I, hermetically closed with pierceable rubber stopper and aluminium caps. The vial with the vaccine is placed in cardboard carton. Multiple packaged vials are placed in a PVC package.

Pack size:
Cardboard box: 1 x 5 doses
Plastic box: 2 x 1 dose, 5 x 1 dose, 10 x 1 dose, 10 x 5 doses

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

Bioveta, a. s.

7. MARKETING AUTHORISATION NUMBER(S)

VPA22028/010/001

8. DATE OF FIRST AUTHORISATION

05/04/2019

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

18/06/2026

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).