1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BioEquin FH emulsion for injection for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:

Each dose 1 ml contains:

Active substances:
Influenza A virus, subtype H3N8, strain A/equine/Brno/08, inactivated min. 6.0 $\log_2$ HIT[1]
Influenza A virus, subtype H3N8, strain A/equine/Limerick/2010, inactivated min. 6.0 $\log_2$ HIT[1]
Equine herpesvirus 1, strain Bio 82, inactivated min. 2.1 $\log_{10}$ VNI[2]

1 The geometric mean of specific antibodies determined by haemagglutination inhibition test in the guinea pig serum
2 The virus neutralization index in the hamster serum

Adjuvant:

Oil adjuvant (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 dihydrogenphosphate	
Disodium hydrogen phosphate dodecahydrate	
Water for injection	
Sodium hydroxide for pH adjustment	

The vaccine is a white, oily liquid 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 of respiratory infections and reduce viral excretion following infection with equine influenza virus and equine herpesvirus 1 (EHV-1).

Onset of immunity has been demonstrated by virulent challenge for equine influenza strain A/Equi 2/Brno 08 and for strain A/Equi 2/ Limerick 2010.

Duration of immunity has been demonstrated by serology for both vaccine influenza strains.

Influenza and Equine Herpesvirus 1
Onset of immunity: 2 weeks after primary vaccination
Duration of immunity: 6 months after the first revaccination (third dose)

For active immunization to reduce the occurrence of abortions in pregnant mares caused by equine herpesvirus 1 (EHV-1) infection:

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

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only. It is recommended not to exercise the horses for 2-3 days after vaccination.

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.

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:

Uncommon (1 to 10 animals / 1 000 animals treated):	Elevated temperature [1]
Rare (1 to 10 animals / 10 000 animals treated):	Injection site swelling [2,3]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Anaphylactic-type reaction[4]

[1] Up to 0.5 °C for 3 days.
[2] Hot and painful, max. 3 days.
[3] In rare occasions, maximum diameters of up to 7-8 cm can occur.
[4] In such a case, symptomatic treatment is required.

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:

Can be used during pregnancy.

Lactation:
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

Vaccine dose - 1 ml. Intramuscular use.
Administer one dose of 1 ml deeply intramuscularly by aseptic method. Before use, allow the vaccine to reach a temperature of 15-25°C and shake well.

Vaccination schedule:
Primary vaccination against equine influenza and herpesvirus:
The first vaccination from 6 months of age; the second vaccination 4 weeks later.

The first revaccination (third dose) is administered 3 months after the primary vaccination course.

Revaccination against equine influenza and herpesvirus:
Subsequent revaccinations are carried out every 6 months.

Vaccination of pregnant mares:
To reduce the incidence of abortions caused by equine herpesvirus infection administer one dose of the vaccine in pregnant mares in the second month after mating, one dose in the fifth or sixth month of pregnancy and one dose during the ninth month of pregnancy.

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 : QI05AA04

For active immunization against equine influenza (clade 1 a and clade 2 Florida sublineage) and 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
Store in a dry place.

5.4 Nature and composition of immediate packaging

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

Pack sizes:
Plastic box with 2 glass vials of 1 dose.
Plastic box with 5 glass vials of 1 dose.
Plastic box with10 glass vials of 1 dose.
Cardboard carton with 1 glass vials of 5 doses.

Plastic box with 10 glass vials of 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)

VPA22028/013/001

8. DATE OF FIRST AUTHORISATION

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

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).