[Version 9.11/2024]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

BioEquin FT suspension for injection for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml dose contains:

Active substances:

Influenza A virus, subtype H3N8, strain A/equine/Limerick/2010, inactivated min. 5 $\log_2$ HIT[1]

Influenza A virus, subtype H3N8, strain A/equine/Brno/08, inactivated min. 5 $\log_2$ HIT[1]

Clostridium tetani, strain Harvard 49205, tetanus toxoid min. 30 IU[2]

[1] Serum antibody titre determined in haemagglutination inhibition test after application of one vaccine dose to guinea pigs.
[2] International units; titre of anti-toxin antibodies, induced after repeated vaccination of guinea pigs according to Ph. Eur., as determined by ELISA.

Adjuvants:
Aluminium hydroxide, hydrated for adsorption 0.2 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 injections	
Sodium hydroxide	
Hydrochloric acid	

White or yellowish to grey-brown suspension. Sediment is formed when the suspension is allowed to stand, but is dispersed by shaking.

3. CLINICAL INFORMATION

3.1 Target species

Horses.

3.2 Indications for use for each target species

For active immunisation of horses against equine influenza to reduce clinical signs and viral excretion following infection with equine influenza virus and for active immunisation and to prevent mortality against tetanus.

Influenza:
Onset of immunity: 2 weeks after basic vaccination
Duration of immunity: 6 months after basic vaccination and 12 months after first revaccination.

The onset of immunity was demonstrated by challenge test for equine influenza strain A/Equi 2/Brno 08 and equine influenza strain A/Equi 2/Limerick 2010.

The duration of immunity of the vaccine equine influenza strains A/Equi 2/Brno08 and A/Equi 2/Limerick 2010 was demonstrated by serology.

Tetanus:
Onset of immunity: 2 weeks after basic vaccination
Duration of immunity: 6 months after basic vaccination and 12 months after first revaccination.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only. It is recommended not to exercise the horse 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Horses:

Very common (>1 animal / 10 animals treated):	Injection site swelling. Elevated temperature.[1]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Injection site abscess, Anaphylactic reaction.[2]

[1] Up to 1 °C for 1-3 days.
[2] 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 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

Vaccine dose - 1 ml. The vaccine is administered by deep intramuscular injection by aseptic method.

The contents of the vial should reach a temperature of 15-25 °C and should be shaken thoroughly before use.

Vaccination schedule:
Basic vaccination:
First vaccination from 6 months of age, second vaccination 4 weeks later.

Revaccination:
First revaccination 6 months after basic vaccination and further revaccination is carried out at the latest at intervals of 12 months.
Revaccination of pregnant mares in the last trimester of pregnancy is carried out not later than one month prior to a scheduled foaling date.

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

Administration of a double recommended dose of the vaccine did not cause any adverse effects.

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

Official control authority batch release may be required for this product according to national requirements.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code : QI05AL01

For active immunisation against tetanus and equine influenza clade 1 and clade 2 Florida sublineage. Active immunisation against tetanus is demonstrated by the serological response (antitoxic antibodies) induced in horses.
When using this vaccine for the first time following another vaccination schedule that did not contain the strains of the same sublineage and clade of equine influenza, it is highly recommended to restart the

vaccination schedule in order to achieve the appropriate level of protection against the strains contained in this vaccine.

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: 33 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 frost.
Protect from light.
Store in a dry place.

5.4 Nature and composition of immediate packaging

The vaccine is provided in type I glass injection vials, sealed hermetically with pierceable rubber stoppers and fitted with aluminium caps.
The vials with the vaccine are placed in cardboard cartons. In bulk packaging the vials are placed in a PVC package.

Pack sizes:
2 vials of 1 dose
5 vials of 1 dose
10 vials of 1 dose
1 vial of 5 doses
10 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)

To be completed nationally

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: DD/MM/YYYY

To be completed nationally

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

{MM/YYYY}
To be completed nationally

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).