

B. PACKAGE LEAFLET

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1. Name of the veterinary medicinal product

BioEquin FT suspension for injection for horses

2. 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
<i>Clostridium tetani</i> , 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.

Adjuvant:

Aluminium hydroxide, hydrated for adsorption 0.2 ml

Excipients:

Thiomersal 0.1 mg

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

3. Target species

Horses.

4. Indications for use

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.

5. Contraindications

None.

6. Special warnings

Special warnings:

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

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.

Pregnancy and lactation:

Can be used during pregnancy.

The safety of the veterinary medicinal product has not been established during lactation.

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.

Overdose

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

Special restrictions for use and special conditions for use:

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

Major incompatibilities:

Do not mix with any other veterinary medicinal product.

7. 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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

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

Vaccination schedule:

Basic vaccination:

First vaccination from 6 months of age, second vaccination 4 weeks later.

Revaccination:

The 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.

9. Advice on correct administration

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

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

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

Protect from frost.

Protect from light.

Store in a dry place.

Do not use this veterinary medicinal product after the expiry date which is stated on the after Exp. The expiry date refers to the last day of that month.

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

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

MA number: *To be completed nationally.*

Pack sizes:

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.

15. Date on which the package leaflet was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse events:

Bioveta, a.s.
Komenského 212/12
68323 Ivanovice na Hané
Czechia
Tel. 00420 517 318 911
email: reklamace@bioveta.cz

Local representatives and contact details to report suspected adverse events:

To be completed nationally.

17. Other information

For active immunisation against tetanus and equine influenza clade 1 and clade 2 Florida sublineage. 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.