

# BioEquin FT, Suspension for injection for horses

## 1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and  
manufacturer responsible for batch release:  
Bioveta a.s.  
Komenského 212/12  
683 23 Ivanovice na Hané  
Czech Republic

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

BioEquin FT, Suspension for injection for  
horses

## 3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

One vaccine dose (1 ml) contains:

### Active substances:

Equine influenza virus, inactivated, strains:  
A/Equi 2/Morava 95 (Eurasian type), H3N8  
min. 5 log<sub>10</sub> HIT<sup>1</sup>

A/Equi 2/Brno 08 (American type, subline  
Florida 2), H3N8 min. 5 log<sub>10</sub> HIT<sup>1</sup>

Tetanus anatoxin, purified min. 30 IU<sup>2</sup>

1. The geometric mean of specific antibodies  
determined by hemagglutination inhibition test  
in the guinea pig serum

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

**Excipient:** 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.

## 4. INDICATION(S)

For active immunisation of horses over six  
months of age against equine influenza to  
reduce clinical signs and viral excretion  
following infection with equine influenza virus  
and for active immunisation against tetanus.

The onset of immunity for equine influenza  
strains A/Equi 2/Brno 08 and A/Equi 2/Morava

95 was demonstrated by challenge test and  
serology, respectively.

The duration of immunity for both vaccine  
strains of equine influenza was demonstrated  
by serology.

**Influenza:**

Onset of immunity: 14 days after basic  
vaccination

Duration of immunity: 6 months after basic  
vaccination and at least 12 months after first  
revaccination (third dose of the vaccine).

**Tetanus:**

Onset of immunity: 14 days after basic  
vaccination

Duration of immunity: 6 months after basic  
vaccination and at least 12 months after first  
revaccination (third dose of the vaccine).

## 5. CONTRAINDICATIONS

Not applicable.

## 6. ADVERSE REACTIONS

A local reaction (swelling at the administration  
site) and/or a slight increase in body  
temperature of up to 1 °C for 1-3 days may be  
observed very frequently in connection with the  
vaccination.

An anaphylactic reaction may occur very rarely.  
In such a case, symptomatic treatment is  
required.

The frequency of adverse reactions is defined  
using the following convention:

- very common (more than 1 in 10 animals  
treated displaying adverse reactions)
- 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).

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  
inform your veterinary surgeon.

## 7. TARGET SPECIES

Horses.

## 8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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

**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 every 12 months.

Pregnant mares are revaccinated in the last  
trimester of pregnancy, but not later than one  
month prior to a scheduled foaling date.

## 9. ADVICE ON CORRECT ADMINISTRATION

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

BioEquin FT should not be used to revaccinate  
horses previously vaccinated with a vaccine  
from a different manufacturer and no vaccine  
from a different manufacturer should be used  
after using BioEquin FT. The exceptions are  
vaccines containing the same strains of equine  
influenza as BioEquin FT.

## 10. WITHDRAWAL PERIOD

Not applicable.

## 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 label.

## 12. SPECIAL WARNING(S)

**Special warnings for each target species:**

In case of increased infection pressure,  
revaccination for equine influenza is  
recommended in all horses of the stud farm  
at an interval of 6 months.

In order to reduce the infection pressure, all  
horses of the stud farm should be  
vaccinated. Before moving horses to  
another stud farm or stable, or before a  
race, at least basic vaccination should be  
performed, with the following 14 days of  
rest necessary to create immunity. At least  
basic vaccination is also recommended as  
part of quarantine for all unvaccinated

horses brought to stud, with the following  
14 days of rest necessary to create  
immunity.

Sick horses with signs of a respiratory  
disease should be stabled and kept  
separately from healthy animals.

Vaccinate only healthy animals.

**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 a practitioner.

**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.

**Incompatibilities:**

Compatibility studies are not available,  
therefore this veterinary medicinal product  
must not be mixed with other veterinary  
medicinal products.

## 13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

## 14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2020

## 15. OTHER INFORMATION

For animal treatment only.

Veterinary medicinal product subject to  
prescription.

Pack sizes:

2 × 1 dose, 5 × 1 dose, 10 × 1 dose,  
1 × 5 doses, 10 × 5 doses

Not all pack sizes may be marketed.



Dimensions (mm): A6 (105 × 148 mm) duplex printing  
Colours: black  
Prepared by: Doleželová  
Date: 16. 12. 2020

Approved by: .....

Date: .....