

BioEquin F, 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 F, suspension for injection for horses

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

One vaccine dose (1 ml) contains:

Active substances:

Inactivated virus equine influenza, strains:
A/Equi 2/Brno 08 (American type, Florida 2),
H3N8 Min. 5 log₂ HIT¹
A/Equi 2/Morava 95 (European type), H3N8
Min. 5 log₂ HIT¹

¹ Geometrical average of specific antibodies
determined by haemagglutination inhibition test
in serum of guinea pigs

Adjuvant(s):

Aluminium hydroxide hydrated for adsorption
0.2 ml

Excipient(s):

Thiomersal 0.1 mg

White or greyish suspension, during storage
can settle down sediment disperses after
shaking.

4. INDICATION(S)

For the active immunization of horses from 6
months of age against equine influenza to
reduce clinical signs and excretion after
infection.

The onset of immunity has been demonstrated
for the challenge test strain of influenza A/Equi
2/Brno 08 and serologically for A/Equi
2/Morava 95.

The duration of immunity for vaccination strains
has been demonstrated serologically.

Onset of active immunity: 14 days after primary
vaccination.

Duration of active immunity: 6 months after
primary vaccination and 12 months after first
revaccination (the third application of vaccine).

5. CONTRAINDICATIONS

Not applicable.

6. ADVERSE REACTIONS

Temporary temperature increase can be
observed after vaccination. Sporadic
anaphylactic reactions may occur.
Symptomatic treatment should be provided in
such a case.

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

- very common (more than 1 in 10 animals
treated displaying adverse reaction(s))
- 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 serious effects or other effects
not mentioned in this package leaflet, or if you
think this medicine is not working, 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 applied deep intramuscularly.

Vaccination schedule:

Primary vaccination:

The first vaccination at the age of 6 months;
the second vaccination 4 weeks later.

Revaccination:

The first revaccination (third dose) is
administered 6 months after the primary
vaccination and next revaccination is carried
out every 12 months.

Revaccination of pregnant mares in the last
trimester of pregnancy is carried out no later
than one month before the planned parturition.

9. ADVICE ON CORRECT ADMINISTRATION

Before use heat the contents of the vial to a
temperature of 15 - 25 °C and shake well.

It is not recommended to use vaccine
BioEquin F for revaccination of horses
previously vaccinated with a vaccine from a
different manufacturer or revaccinated vaccine
BioEquin F by vaccine from different
manufacturer. Exceptions are vaccines
containing the same strains of equine influenza
as BioEquin F.

10. WITHDRAWAL PERIOD

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
label.

12. SPECIAL WARNING(S)

Special warnings for each target species:

Vaccinate healthy animals only.

Special precautions for use in animals:

In case of increased infection risk is
recommended revaccination against equine
influenza every 6 months and that in all horses
in breeding.

In order to reduce infection pressure should
vaccinate all horses at stud. At least primary
vaccination, with the following 14 days of rest
necessary to create immunity, should be
performed before transfers of horses to other
herds or stables, or before races. Primary
vaccination, with the following 14 days of rest
necessary to create immunity, is recommended
during the quarantine period for all
unvaccinated horses to be included in
breeding.

Sick horses with signs of a respiratory disease
should be isolated from healthy animals.

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:

In the absence of compatibility studies, 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

Any unused veterinary medicinal product or
waste materials derived from such veterinary
medicinal product should be disposed of in
accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

February 2021

15. OTHER INFORMATION

For animal treatment only.

To be supplied only on veterinary prescription.
For use by veterinary surgeons only.

Pack size: 2 × 1 dose, 5 × 1 dose, 10 × 1 dose
1 × 5 doses, 10 × 5 doses

Not all pack sizes may be marketed.



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Monika

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