

BioEquin H, emulsion 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 H, emulsion for injection for horses

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

One dose (1 ml) of the vaccine contains:

Active substance:

Inactivated equine herpes virus type 1, (EHV-1)

Min. 2.1 log₁₀ VNI¹

¹ Virus neutralization index determined in
serum of hamsters

Adjuvant:

Oil adjuvant (Montanide ISA 35 VG) 0.25 ml

Excipient:

Thiomersal 0.1 mg

The vaccine is an oily liquid, creamy white,
yellowish or pale pink colour, with easily
shakeable sediment.

4. INDICATION(S)

For the active immunization of horses to
reduce the incidence of respiratory infections
and clinical symptoms caused by equine
herpesvirus type 1 (EHV-1) and to reduce the
occurrence of abortions in pregnant mares
caused by equine herpesvirus type 1 (EHV-1)
infection.

Onset of Immunity: 2 weeks after primary
vaccination

Duration of Immunity: 6 months after
revaccination

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

Temporary temperature increase (max. 40°C
for 4 days) observed after vaccination is very
common.

Local reactions maximally 5 × 10 cm for period
of 5 days may occur rarely. Anaphylactic
reaction is very rare. 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
displaying adverse reaction(s) during the
course of one treatment)

- common (more than 1 but less than
10 animals in 100 animals)

- uncommon (more than 1 but less than
10 animals in 1,000 animals)

- rare (more than 1 but less than 10 animals
in 10,000 animals)

- very rare (less than 1 animal in 10,000
animals, including isolated reports).

If you notice any serious effects or other effects
not mentioned in this package leaflet, please
inform your veterinary surgeon.

7. TARGET SPECIES

Horses.

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

Administer the vaccine dose (1 ml) deep
intramuscularly.

Vaccination schedule - Primary vaccination:

The basic immunisation consists of two
vaccinations: the first vaccination at the age
of 6 months; the second vaccination 4 weeks
later.

Revaccination:

The first revaccination (third dose) is
administered 3 months after the second
injection of primary vaccination. Next
revaccinations to be carried out every
6 months.

Vaccination pregnant mares:

To reduce the incidence of abortions caused by
equine herpesvirus infection one dose of the
vaccine is administered to pregnant mares in
the second month after mating and then in the
fifth or sixth month and in the ninth month of
pregnancy.

9. ADVICE ON CORRECT ADMINISTRATION

Before use, the contents of the vial warm up a
temperature of 15 - 25 °C and the content of
the vial shaken well.

10. SPECIAL PRECAUTIONS

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 light.

Store in a dry place.

Do not use this veterinary medicinal product
after the expiry date which is stated on the
label after EXP.

Shelf-life after first opening the container:
10 hours

12. SPECIAL WARNING(S)a

Special warnings for each target species:

In order to reduce the infection pressure, all
horses on a farm should be vaccinated. 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. Regular
vaccination of all animals in a breeding facility,
with observance of prescribed deadlines, is
necessary to create and maintain immunity
from equine herpesvirus infections. 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

Special precautions for use in animals:

Only healthy animals should be vaccinated.

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 the physician.

To the user:

This veterinary medicinal product contains
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
mineral oil. Even if small amounts have been
injected, accidental injection with this 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.

Pregnancy:

Can be used during pregnancy.

Lactation:

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 products should be disposed of in
accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

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

Not all pack sizes may be marketed.

For any information about this veterinary
medicinal product, please contact the local
representative of the marketing authorisation
holder.

bioveta