ANNEX III

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
1 x 5 doses / carton
2 x 1 dose, 5 x 1 dose, 10 x 1 dose, 10 x 5 doses / plastic box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EquiShield EHV, emulsion for injection for horses

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

One dose (1 ml) contains:
Active substance:
Inactivated equine herpes virus type 1, (Bio 82: EHV – 1) Min. 2.1 $\log_{10}$ VNI

Adjuvant:
Montanide ISA 35 VG
Excipient:
Thiomersal

3. PHARMACEUTICAL FORM

Emulsion for injection.

4. PACKAGE SIZE

2 x 1 dose / 5 x 1 dose / 10 x 1 dose / 1 x 5 doses / 10 x 5 doses

5. TARGET SPECIES

Horses

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.
Accidental injection is dangerous.

In case of accidental self-injection seek medical advice immediately and show the package leaflet or label to the physician.

10. EXPIRY DATE

EXP {month/year}
Once opened use by 10 hours.

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.
Protect from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.
To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Dechra Regulatory B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

Vm 50406/5003

17. MANUFACTURER'S BATCH NUMBER

Batch{number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{1 dose; 5 doses / glass vial}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EquiShield EHV, emulsion for injection for horses

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Inactivated equine herpes virus type 1, (Bio 82: EHV-1) Min. 2.1 $\log_{10}$ VNI

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 dose / 5 doses

4. ROUTE(S) OF ADMINISTRATION

i.m.

5. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}
Once opened use by 10 hours.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

EquiShield EHV, 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:
Dechra Regulatory B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

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

EquiShield EHV, 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, (Bio 82: EHV-1) Min. 2.1 $\log_{10}$ VNI[1]
1 Virus neutralization index determined in serum of hamsters

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 clinical signs and to reduce virus excretion during respiratory disease caused by equine herpesvirus type 1 (EHV-1) infections.

Onset of immunity: 2 weeks after the second vaccine injection

Duration of immunity has only been demonstrated after the administration of three vaccine injections (see section 8): 6 months after the 3rd vaccine injection.

For active immunisation of pregnant mares to reduce the occurrence of abortions caused by equine herpesvirus type 1 (EHV-1) infections.

Onset of immunity: 3 weeks after the 3rd vaccine injection during gestation
Duration of immunity: until the end of pregnancy.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

The following was reported based on post-marketing surveillance experience:
Temporary temperature increases (at max. 40°C for 4 days) are very common after vaccination. The development of local reactions that may reach up to 5x10 cm diameter are rare and persist for a maximum of 5 days. Anaphylactic reaction is very rare. Symptomatic treatment should be provided.

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 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

For intramuscular use: administer the vaccine dose (1 ml) by deep intramuscular injection.

Vaccination schedule - primary vaccination:
The basic immunisation schedule consists of three vaccine injections: the first injection from the age of 6 months; the second injection 4 weeks later, and the third injection 3 months after the second dose.

Revaccination:
Administer one dose of vaccine 6 months after completion of the primary vaccination schedule, and thereafter every 6 months.
Vaccination of pregnant mares:

To reduce the incidence of abortions, administer one dose of the vaccine in the second month after mating, one dose in the fifth or sixth month of pregnancy, and one dose in the ninth month of pregnancy.
The three dose vaccination scheme should be repeated for subsequent pregnancies.

9. ADVICE ON CORRECT ADMINISTRATION

Before use, allow the vaccine to reach a temperature of 15-25°C.
Shake well before use.

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 light.

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)

Special warnings for each target species:
In order to reduce the infection pressure, all horses on the same premises should be vaccinated. Before transfer of horses to other herds or stables, or before races, vaccination should be performed allowing for at least 14 days for onset of immunity. Before inclusion in a herd, horses should be vaccinated and kept in quarantine until onset of immunity is reached. Sick horses with signs of a respiratory disease should be isolated from healthy animals.
Vaccinate healthy animals only.

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 non-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 non-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:
Do not mix with any other veterinary medicinal product.

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 x 1 dose, 5 x 1 dose, 10 x 1 dose,
1 x 5 doses, 10 x 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.

For animal treatment only.
To be supplied only on veterinary prescription.

Approved 01 March 2023