SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EquiShield EHV, emulsion for injection for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One vaccine dose (1 ml) 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

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

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

4. CLINICAL PARTICULARS

4.1 Target species

Horses.

4.2 Indications for use, specifying the target species

For 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 4.9): 6 months after the 3rd vaccine injection.

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

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

4.3 Contraindications

None.

4.4 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.

4.5 Special precautions for use

Special precautions for use in animals

None.

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.

4.6 Adverse reactions (frequency and seriousness)

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).

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy.
The safety of the veterinary medicinal product has not been established during lactation.

4.8 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.

4.9 Amounts to be administered and administration route

For intramuscular use: administer the vaccine dose (1 ml) by deep intramuscularinjection.
Before use, allow the vaccine to reach a temperature of 15-25°C.
Shake well before use.

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Not applicable.

4.11 Withdrawal periods

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Inactivated viral vaccines for horses
ATC vet code: QI05AA05

For active immunization against equine herpesvirus.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Montanide ISA 35 VG
Thiomersal
Sodium chloride
Potassium chloride
Potassium dihydrogen phosphate
Disodium hydrogen phosphate dodecahydrate
Water for injections
Sodium hydroxide (for pH adjustment)

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 18 months.
Shelf-life after first opening the immediate packaging: 10 hours.

6.4 Special precautions for storage

Store in a refrigerator (2°C - 8°C).
Protect from light.

6.5 Nature and composition of immediate packaging

The vaccine is filled in glass vials of hydrolytic class I, hermetically closed with pierceable rubber stopper and aluminium caps. The vial with the vaccine are placed in cardboard carton. Multiple packaged vials are placed in a PVC package.

Pack size:
Cardboard box: 1 x 5 doses
Plastic box: 2 x 1 dose, 5 x 1 dose, 10 x 1 dose, 10 x 5 doses

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such product

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

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 50406/5003

9. DATE OF FIRST AUTHORISATION

01 March 2023

10. DATE OF REVISION OF THE TEXT

March 2023

PROHIBITION OF SALE, SUPPLY AND/OR USE

OTHER INFORMATION

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

Approved 01 March 2023