SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equip EHV1,4

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:
Inactivated EHV_1, strain 438/77:RP ≥ 1*
Inactivated EHV_4, strain 405/76:RP ≥ 1*

Relative Potency ELISA compared to a reference vaccine which has been shown to be efficacious in horses.

Adjuvant(s):
Carbopol 934P : 6 mg

Excipient(s):

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection

4. CLINICAL PARTICULARS

4.1 Target species

Horses.

4.2 Indications for use, specifying the target species

For active immunisation of horses to reduce clinical signs due to infection with Equine Herpesvirus 1 and 4 and to reduce abortion caused by EHV-1 infection.

4.3 Contraindications

Do not vaccinate unhealthy horses.

4.4 Special warnings

None known.

4.5 Special precautions for use

i. Special precautions for use in animals

Syringes and needles should not have been sterilised chemically or be above ambient temperature. Do not use chemicals to disinfect or sterilise the skin

ii. Special precautions to be taken by the person administering the veterinary medicinal product to animals

None

4.6 Adverse reactions (frequency and seriousness)

A transient local swelling at the injection site was very commonly observed. Usually, the local swelling does not measure more than 5 cm in diameter and disappears within a few to 6 days post vaccination. A transient increase in rectal temperature during up to 2 days following dosing not exceeding 1.7°C was commonly observed. These clinical signs usually resolve with no need for treatment.
Rarely, stiff gait, anorexia and lethargy have been reported. Hypersensitivity reactions may occur in very rare cases. In case of such reactions, appropriate treatment is recommended.

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.

4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the compatibility of this vaccine with any other. Therefore the safety and efficacy of this product when used with any other (either when used on the same day or at different times) has not been demonstrated.

4.9 Amounts to be administered and administration route

One dose per horse to be administered by deep intramuscular injection.

Primary course: A single dose should be administered from 5 months of age followed by a second injection after an interval of 4 to 6 weeks.

In the event of increased infection risk, for example when a foal had consumed insufficient colostrum or there is a risk of early exposure to field infections with EHV-1 or EHV-4, earlier vaccination may be given. In these circumstances, the foal should receive a single dose from 3 months of age followed by the above mentioned full primary vaccination course.

Booster: Following completion of the primary course, a single dose should be administered every 6 months.

Use in pregnant mares: To reduce abortion due to EHV-1 infection, pregnant mares should be vaccinated during the 5th, 7th and 9th month of pregnancy with a single 1.5 ml dose on each occasion

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

No adverse reactions exceeding those discussed in section 4.6 were recorded following administration of an overdose.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

To stimulate active immunity against equine herpesvirus 1 and 4.

ATC Vet Code: QI05AA05

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carbopol 934P
Disodium hydrogen phosphate
Sodium dihydrogen phosphate
Water for injection

6.2 Incompatibilities

Do not mix with any other medicinal product.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.

6.4 Special precautions for storage

The vaccine has to be stored and transported in its original unopened undamaged packing in the dark at +2°C-+8°C. Exposure to heat and/or direct sunlight has to be avoided. Do not freeze.

6.5 Nature and composition of immediate packaging

Single dose (1.5 ml)
Container: Type 1 glass Ph.Eur
Closure: Chlorobutyl rubber stopper PH 21/50 (Ph.Eur.). Aluminium crimp cap.

Pack sizes: 2, 10 and 50 dose packs
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 products

Dispose of waste material by incineration or immersion in an appropriate disinfectant approved for use by the competent authorities.

7. MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A.
2nd Floor, Building 10
Cherrywood Business Park
Loughlinstown
Co. Dublin
Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 60021/3009

9. DATE OF FIRST AUTHORISATION

14 December 1994

10. DATE OF REVISION OF THE TEXT

November 2024

Gavin Hall

Approved 14 November 2024