1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equip EHV 1,4 Suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Equine herpesvirus vaccine (inactivated)

Each 1.5 ml dose contains:

Active substances:
Inactivated EHV type 1, strain 438/77, inactivated: RP $\geq$ 1*
Inactivated EHV type 4, strain 405/76, inactivated: RP $\geq$ 1*

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

Adjuvant:

Carbopol 934P 6 mg

Excipients:

Qualitative composition of excipients and other constituents
Disodium hydrogen phosphate dihydrate
Sodium dihydrogen phosphate dihydrate
Phosphate buffer

Watery, colourless to slightly pink/orange opaque suspension for injection

3. CLINICAL INFORMATION

3.1 Target species

Horses and ponies.

3.2 Indications for use for each target species

For the active immunisation of horses and ponies to reduce the incidence of respiratory disease and viral shedding caused by infection with equine herpesvirus types 1 and 4 (EHV-1 and EHV-4) and to reduce the incidence of abortion caused by infection with EHV-1.

Onset of immunity: 2 weeks after primary vaccination course.

Protection against virulent challenge has been demonstrated within 3 weeks.

Duration of immunity: 6 months.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Maternally derived antibody (MDA) may persist in foals up to the age of 5 months and may interfere with the development of active immunity in foals vaccinated between the ages of 3 and 5 months. Please see section 3.9 for advice on vaccination of foals under the age of 5 months.

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

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

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Horses and Ponies:

Rare (1 to 10 animals / 10,000 animals treated):	Injection site swelling[1,2] Stiff gait[2] Anorexia, hyperthermia, lethargy[2]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site abscess Anaphylactic-type reaction

[1] Does not usually measure more than 5 cm in diameter and can be painful on occasion.
[2] The observed clinical signs usually disappear within a few to 10 days post vaccination without treatment.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:

Can be used during pregnancy.

3.8 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.

3.9 Administration routes and dosage

Intramuscular use.

One 1.5 ml dose per horse to be administered by deep intramuscular injection.

Shake well before use.
Aseptic precautions should be observed.

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, an 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 the incidence of 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No adverse reactions exceeding those discussed in section 3.6 were recorded following administration of an overdose.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATC vet code:

QI05AA05.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities
Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: use immediately.

5.3 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Protect from light.

5.4 Nature and composition of immediate packaging

Single dose vials (1.5 ml).
Closure: Chlorobutyl rubber stopper Ph.Eur. Aluminium crimp cap. Vial: Type I (Ph.Eur.) glass.3 ml capacity

The vaccine is presented in cartons containing 1, 2, 3 or 10 doses.

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10387/028/001

8. DATE OF FIRST AUTHORISATION

26/09/2014

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

18/12/2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.
Detailed information on this veterinary medicinal product is available in the Union Product Database. (*https://medicines.health.europa.eu/veterinary*).