1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Equip EHV 1,4 Suspension for injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Equine herpesvirus vaccine (inactivated)

One dose (1.5ml) contains

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

Adjuvants
Carbopol 934P 6 mg

Excipients:
For a full list of excipients, see section 6.1
*Relative Potency ELISA compared to a reference vaccine which has been shown to be efficacious in horses

3 PHARMACEUTICAL FORM

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

4 CLINICAL PARTICULARS

4.1 Target Species

Horses and ponies.

4.2 Indications for use, specifying the 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. After completion of the primary vaccination course, the presence of antibodies has been demonstrated within 2 weeks and protection against virulent challenge has been demonstrated within 3 weeks. The duration of immunity is 6 months.

4.3 Contraindications

Do not vaccinate unhealthy horses.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals:
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 4.9 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 the case of accidental self-injection, ingestion or spillage onto skin, seek medical advice and show the package leaflet or label to the physician.

4.6 Adverse reactions (frequency and seriousness)

In rare cases mild transient injection site reactions (swelling), stiff gait and systemic reactions (anorexia, hyperthermia and lethargy) have been reported. Injection site swelling does not usually measure more than 5 cm in diameter and can be painful on occasion. The observed clinical signs usually disappear within a few to 10 days post vaccination without treatment. On very rare occasions, abscessation at the injection site may be observed after vaccination. As with other vaccines, anaphylactic-like reactions may occur in very rare cases.

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 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

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.

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 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for equidae, horse, inactivated viral vaccines, equine rhinopneumonitis virus

ATC Vet Code: QI05AA05

To stimulate active immunity against equine herpesvirus types 1 and 4.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carbopol 934P
Disodium hydrogen phosphate dihydrate
Sodium dihydrogen phosphatedihydrate
Phosphate buffer

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf-life

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

6.4 Special precautions for storage

Store and transport refrigerated at +2°C-+8°C.
Protect from light.
Do not freeze.

6.5 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.

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

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

7 MARKETING AUTHORISATION HOLDER

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

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10387/028/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21st April 2011
Date of last renewal: 6th December 2012

10 DATE OF REVISION OF THE TEXT

November 2017