ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Equip EHV 1,4 – Carton
10x 1 dose

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equip EHV 1,4

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Inactivated adjuvanted equine herpes vaccine
Inactivated EHV1, strain 438/77 RP ≥ 1
Inactivated EHV4, strain 405/76 RP ≥ 1
and 6 mg Carbopol 934P as adjuvant

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

10x 1 dose

5. TARGET SPECIES

Horses

6. INDICATION(S)

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.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

One dose per horse to be administered by deep intramuscular injection.
Syringes and needles should not have been sterilised chemically or be above ambient temperature. Do not use chemicals to disinfect the skin.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use

10. EXPIRY DATE

Exp:

11. SPECIAL STORAGE CONDITIONS

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

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

Read the package leaflet before use

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

For animal treatment only.

POM-V
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

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4060

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Equip EHV 1,4 – vial label
1 dose

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equip EHV 1,4

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Inactivated adjuvanted equine herpes vaccine

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

1 dose

4. ROUTE(S) OF ADMINISTRATION

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5. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

Exp.:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.
Store at +2°C - +8°C.
Keep the container in the outer carton.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
Equip EHV 1,4

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder :
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

Manufacturer responsible for batch release:
Zoetis Manufacturing & Research Spain, S.L.
Ctra. Camprodon s/n “La Riba”
17813 Vall de Bianya, Girona
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equip EHV 1,4
Suspension for injection

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Inactivated EHV1, strain 438/77 RP* ≥ 1
Inactivated EHV4, strain 405/76 RP* ≥ 1
and 6 mg Carbopol 934P as adjuvant

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

4. INDICATION(S)

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.

5. CONTRAINDICATIONS

Do not vaccinate unhealthy horses.
Can be used during pregnancy.
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.
Do not mix with any other vaccine or immunological product.
The vaccine may not be effective in animals incubating the disease at the time of vaccination.

In the event of an allergic or anaphylactic reaction, immediate treatment should be given with a soluble glucocorticoid intravenously (e.g. dexamethasone sodium phosphate), adrenaline intramuscularly or anti-histamine intramuscularly.
Animals that have received immunosuppressive drugs (e.g. glucocorticoids) should not be vaccinated until an interval of at least 4 weeks has elapsed.

6. ADVERSE REACTIONS

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.

7. TARGET SPECIES

Horses.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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

9. ADVICE ON CORRECT ADMINISTRATION

Syringes and needles should not have been sterilised chemically or be above ambient temperature. Do not use chemicals to disinfect or sterilise the skin.
Shake well before use.
Aseptic precautions should be observed.

10. WITHDRAWAL PERIOD

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

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

12. SPECIAL WARNING(S)

None.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2020

15. OTHER INFORMATION

For Animal Treatment Only.
Equine Herpesvirus (EHV) is associated with respiratory disease, abortions, perinatal mortality and, occasionally, neurological disorders.
EHV disease has a complex epidemiology. Clinically and subclinically infected horses and latent carriers may excrete virus.
Epizootics of herpesvirus disease are most commonly associated with management activities that bring together in close proximity large numbers of horses under conditions that produce stress; i.e. weaning, transport and intermingling of horses originating from diverse locations.
Abortion due to EHV infection usually occurs in the last 4 months of gestation but the time interval between infection and abortion may be several weeks.
Effective control of EHV induced respiratory disease and abortions involves application of carefully executed management practices, including vaccination to minimise the spread of disease and the level of virus challenge.
It is recommended to vaccinate all horses on the premises, according to the recommendations of the datasheet.

If horses are not vaccinated in accordance with the datasheet recommendations for Equip EHV 1,4 the immune responses may be impaired.
The primary vaccination programme against respiratory disease has been developed to coincide with the expected decline of maternally derived antibody (MDA). In some foals MDA can decline earlier than 5 months of age, for example when regular

booster vaccination of the dam has not taken place, or when there has been no recent field infection. Under these circumstances, the timing of the vaccination programme should be planned accordingly.
This vaccine does not prevent respiratory disease, abortion or perinatal mortality caused by other agents.
In any animal population there will be a small number of individuals which fail to respond fully to vaccination. Successful vaccination depends upon correct storage and administration of the vaccine and the animal's ability to respond. Immune competence can be influenced by genetic factors, intercurrent infection, age, nutritional status, concurrent drug therapy, stress, etc.

PACKAGE QUANTITIES
2, 10 and 50 dose packs
Not all pack sizes may be marketed.

LEGAL CATEGORY
POM-V
Prescription Only Medicine – Veterinarian
To be supplied only on veterinary prescription

MARKETING AUTHORISATION NUMBER
Vm 42058/4060

Approved 19 August 2020