PARTICULARS TO APPEAR ON THE OUTER PACKAGE – Cardboard Box of 2, 4 or 10 single-dose pre-filled syringes

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equip WNV emulsion for injection for horses

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml contains:

Inactivated West Nile virus, strain VM-2 (1.0–2.2 RP).

3. PACKAGE SIZE

2 single-dose syringes
4 single-dose syringes
10 single-dose syringes

4. TARGET SPECIES

Horses

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited

14. MARKETING AUTHORISATION NUMBERS

Vm 42058/5023

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

POM-V Veterinary medicinal product subject to prescription

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {single dose syringe}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equip WNV emulsion for injection for horses

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Inactivated West Nile virus

1 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

5. ROUTE(S) OF ADMINISTRATION

IM

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equip WNV emulsion for injection for horses

2. COMPOSITION

Each 1 ml dose contains:

Active substance:

Inactivated West Nile virus, strain VM-2	1.0–2.2 RP*

Adjuvant:

SP oil	4.0% - 5.5% (v/v).

* Relative potency by in vitro method, compared to a reference vaccine that was shown efficacious in horses.

Slight pink opaque emulsion for injection.

3. TARGET SPECIES

Horses.

4. INDICATIONS FOR USE

For the active immunisation of horses of 6 months of age or older against West Nile virus (WNV) disease by reducing the number of viraemic horses after infection with WNV lineage 1 or 2 strains and to reduce duration and severity of clinical signs against WNV of lineage 2 strains.

Onset of immunity: 3 weeks after primary vaccination course.
Duration of immunity: 12 months after primary vaccination course for WNV lineage 1 strains. For WNV lineage 2 strains the duration of immunity has not been established.

5. CONTRAINDICATIONS

None.

6. SPECIAL WARNINGS

Special warnings:
Vaccinate healthy animals only.

Special precautions for safe use in the target species:
Vaccination may interfere with existing sero-epidemiological surveys. However, since the IgM response following vaccination is infrequent, a positive IgM-ELISA test result is a strong indicator of natural infection with West Nile virus. If infection is suspected

as a result of a positive IgM response, additional testing would need to be conducted to conclusively determine whether the animal was infected or vaccinated.

No specific studies have been conducted to demonstrate absence of interferences from maternally derived antibodies on vaccine take. It is therefore recommended not to vaccinate foals of less than 6 months of age.

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 the label to the physician.

Special precautions for the protection of the environment:
Not applicable.

Pregnancy and lactation:
The vaccine can be used during pregnancy and lactation. However, no specific efficacy studies were conducted in pregnant mares. As a consequence, it cannot be excluded that transient immunodepression that may be observed during pregnancy could interfere with vaccine uptake.

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.

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

The use of Equip WNV reduces the number of animals with viraemia after natural infection, but may not systematically prevent it.

7. ADVERSE EVENTS

Horses:

Rare (1 to 10 animals / 10,000 animals treated):
Hypersensitivity reaction (including vomiting, incoordination, lethargy and laboured breathing)[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Hyperthermia[2] Injection site swelling (sometimes associated with injection site pain and mild depression)[3]

[1]As with any vaccine rare, occasional hypersensitivity reactions may occur. If such a reaction occurs, appropriate treatment should be administered without delay.
[2]Resolves within 2 days
[3]Transient local reactions in the form of a mild, local swelling at the injection site post vaccination (maximum 1 cm in diameter) that resolve spontaneously within 1 to 2 days.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system. {national system details}

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Intramuscular use.

Administer the entire content of the syringe (1 ml), by deep intramuscular injection in the neck region, according to the following schedule:

- Primary vaccination course: first injection from 6 months of age, second injection 3–5 weeks later.
- Revaccination: a sufficient degree of protection should be achieved after an annual booster injection with a single 1 ml dose although this schedule has not been fully validated.

9. ADVICE ON CORRECT ADMINISTRATION

Not applicable.

10. WITHDRAWAL PERIODS

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store and transport refrigerated (2 °C–8 °C).
Do not freeze.
Protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

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

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 42058/5023

Single-dose (1 ml) pre-filled type I glass syringe closed with bromobutyl rubber tip.
Packaging: box of 2, 4 or 10 single-dose syringes with needles.

Not all pack sizes may be marketed.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

October 2023

Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder and contact details to report suspected adverse reactions:
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey, KT22 7LP
UK
Tel: +44 (0) 345 300 8034

Manufacturer responsible for batch release:
Zoetis Belgium
Rue Laid Burniat 1
1348 Louvain-La-Neuve
BELGIUM

17. OTHER INFORMATION

POM-V Veterinary medicinal product subject to prescription

For animal treatment only.

Approved 01 March 2024