SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equip WNV emulsion for injection for horses

2. QUALITATIVE AND QUANTITATIVE 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.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Slight pink opaque emulsion for injection.

4. CLINICAL PARTICULARS

4.1 Target species

Horses.

4.2 Indications for use, specifying the target species

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.

4.3 Contraindications

None

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals
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.

Other precautions
Not applicable.

4.6 Adverse reactions (frequency and seriousness)

Horses:

Rare (1 to 10 animals / 10,0000 animals treated):	Hypersensitivity reaction[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 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 contact details.

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation.

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.

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 Amount(s) to be administered and administration route

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.

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

Following the administration of a double dose of vaccine, no adverse reactions other than those described under section 4.6 have been observed.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

ATCvet code: QI05AA10.

Immunologicals for Equidae, inactivated viral vaccines for horses.

The vaccine stimulates active immunity against West Nile virus.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Minimum essential medium (MEM)
Phosphate buffered saline
SP oil

6.2 Major Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

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

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

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.

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

Medicines should not be disposed of via wastewater.

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

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 42058/5023

9. DATE OF FIRST AUTHORISATION

21 November 2008

10. DATE OF REVISION OF THE TEXT

December 2024

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

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

Gavin Hall

Approved: 19 January 2025