

**ANNEX I**  
**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.

### Excipients:

Qualitative composition of excipients and other constituents
Minimum essential medium (MEM)
Phosphate buffered saline

Slight pink opaque emulsion.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Horses.

### 3.2 Indications for use for each 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.

### 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:

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.

### 3.6 Adverse events

Horses:

Rare (1 to 10 animals / 10,000 animals treated):	Hypersensitivity reaction <sup>1</sup>
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hyperthermia <sup>2</sup>
	Injection site swelling (sometimes associated with injection site pain and mild depression) <sup>3</sup>

<sup>1</sup> As with any vaccine rare, occasional hypersensitivity reactions may occur. If such a reaction occurs, appropriate treatment should be administered without delay.

<sup>2</sup> Resolves within 2 days.

<sup>3</sup> 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 respective contact details.

### 3.7 Use during pregnancy, lactation or lay

#### Pregnancy and lactation:

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.

### **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**

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.

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

Following the administration of a double dose of vaccine, no adverse reactions other than those described under section 3.6 have been observed.

### **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**

Any person intending to manufacture, import, possess, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

### **3.12 Withdrawal periods**

Zero days.

## **4. IMMUNOLOGICAL INFORMATION**

### **4.1 ATCvet code: QI05AA10**

Immunologicals for Equidae, inactivated viral vaccines for horses.  
The vaccine stimulates active immunity against West Nile virus.

## **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: 2 years.

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

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

### **7. MARKETING AUTHORISATION NUMBER(S)**

EU/2/08/086/004–006

### **8. DATE OF FIRST AUTHORISATION**

Date of first authorisation: 21/11/2008.

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

{MM/YYYY}

### **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.

**ANNEX II**

**OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION**

None

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**



**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 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**

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 Belgium

**14. MARKETING AUTHORISATION NUMBERS**

EU/2/08/086/004 (2 single-dose glass syringes)  
EU/2/08/086/005 (4 single-dose glass syringes)  
EU/2/08/086/006 (10 single-dose glass syringes)

**15. BATCH NUMBER**

Lot {number}

**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. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

Inactivated West Nile virus.

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}

**B. PACKAGE LEAFLET**

## 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.

### 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.

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

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.

Special restrictions for use and special conditions for use:

Any person intending to manufacture, import, possess, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

Major incompatibilities:

Do not mix with any other veterinary medicinal product.

## **7. Adverse events**

Horses:

Rare (1 to 10 animals / 10,000 animals treated):
Hypersensitivity reaction <sup>1</sup>
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
-Hyperthermia <sup>2</sup>
-Injection site swelling (sometimes associated with injection site pain and mild depression) <sup>3</sup>

<sup>1</sup> As with any vaccine rare, occasional hypersensitivity reactions may occur. If such a reaction occurs, appropriate treatment should be administered without delay.

<sup>2</sup> Resolves within 2 days

<sup>3</sup> 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 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 applicable national collection systems. These measures should help to protect the environment.

## **13. Classification of veterinary medicinal products**

Veterinary medicinal product subject to prescription.

## **14. Marketing authorisation numbers and pack sizes**

EU/2/08/086/004 – 006

Single-dose (1 ml) pre-filled type I glass syringe closed with bromobutyl rubber tip.

Packaging: cardboard 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**

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database.

**16. Contact details**

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

Zoetis Belgium  
Rue Laid Burniat 1  
1348 Louvain-La-Neuve  
Belgium

**België/Belgique/Belgien**  
Tél/Tel: +32 (0) 800 99 189  
[pharmvig-belux@zoetis.com](mailto:pharmvig-belux@zoetis.com)

**Република България**  
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