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 (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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See also the last section of 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

DD/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 (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 local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

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

DD/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:

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

Local representatives and contact details to report suspected adverse reactions:

België/Belgique/Belgien
Zoetis Belgium
Mercuriusstraat 20
BE-1930 Zaventem
Tél/Tel: +32 (0) 800 99 189

Република България
Zoetis Belgium
Rue Laid Burniat 1
1348 Louvain-La-Neuve
Белгия
Тел: +359 888 51 30 30

Česká republika
Zoetis Česká republika, s.r.o.
náměstí 14. října 642/17
CZ 150 00 Praha
Tel: +420 257 101 111

Danmark
Zoetis Animal Health ApS
Øster Alle 48
DK-2100 København
Tlf: +45 70 20 73 05
adr.scandinavia@zoetis.com

Deutschland
Zoetis Deutschland GmbH
Schellingstr. 1
DE-10785 Berlin
Tel: +49 30 2020 0049
tierarzneimittelsicherheit@zoetis.com

Lietuva
Zoetis Belgium
Mercuriusstraat 20
1930 Zaventem
Belgija
Tel: +370 610 05088

Luxembourg/Luxemburg
Zoetis Belgium
Mercuriusstraat 20
1930 Zaventem
Belsch
Tél/Tel: +32 (2) 746 80 11

Magyarország
Zoetis Hungary Kft.
Csörsz u. 41.
HU-1124 Budapest
Tel.: +36 1 224 5200

Malta
Agrimed Limited
Mdina Road, Zebbug ZBG 9016,
MT
Tel: +356 21 465 797

Nederland
Zoetis B.V.
Rivium Westlaan 74
NL-2909 LD Capelle aan den IJssel
Tel: +31 (0)10 714 0900

Eesti
Zoetis Belgium
Mercuriusstraat 20
1930 Zaventem
Belgia
Tel: +370 610 05088

Ελλάδα
Zoetis Hellas S.A.
Φραγκοκκλησιάς 7, Μαρούσι
EL-15125 Αττική
Τηλ: +30 210 6791900

España
Zoetis Spain, S.L.
Parque Empresarial Vía Norte Edificio nº1,
c/ Quintanavides nº13
ES-28050 Madrid
Tel: +34 91 4191900

France
Zoetis France
10 rue Raymond David
FR-92240 Malakoff
Tél: +33 (0)800 73 00 65

Hrvatska
Zoetis B.V.
Podružnica Zagreb za promidžbu
Petra Hektorovića 2
HR-10000 Zagreb
Tel: +385 1 6441 462

Ireland
Zoetis Belgium S.A. (Irish Branch)
2nd Floor, Building 10,
Cherrywood Business Park,
Loughlinstown,
Co. Dublin,
IE – Dublin D18 T3Y1
Tel: +353 (0) 1 256 9800

Ísland
Zoetis Animal Health ApS
Øster Alle 48
DK-2100 København
Danmörku
Sími: +45 70 20 73 05
adr.scandinavia@zoetis.com

Norge
Zoetis Animal Health ApS
Øster Alle 48
DK-2100 København
Danmark
Tlf: +47 23 29 86 80
adr.scandinavia@zoetis.com

Österreich
Zoetis Österreich GmbH
Floridsdorfer Hauptstr. 1
AT-1210 Wien
Tel: +43 (0)1 2701100 100
tierarzneimittelsicherheit@zoetis.com

Polska
Zoetis Polska Sp. z o.o.
ul. Postępu 17B
PL - 02-676 Warszawa
Tel.: +48 22 2234800

Portugal
Zoetis Portugal Lda.
Lagoas Park, Edifício 10
PT-2740-271 Porto Salvo
Tel: +351 21 042 72 00

România
Zoetis România S.R.L.
Expo Business Park, 54A Aviator
Popișteanu, Clădirea 2, Etaj 1-3,
Sector 1,
București, 012095 - RO
Tel: +40785019479

Slovenija
Zoetis B.V.
Podružnica Zagreb za promidžbu
Petra Hektorovića 2,
10000 Zagreb,
Hrvaška
Tel: +385 1 6441 462

Slovenská republika
Zoetis Česká republika, s.r.o.
náměstí 14. října 642/17
150 00 Praha
Česká republika
Tel: +420 257 101 111

Italia
Zoetis Italia S.r.l.
Via Andrea Doria 41M,
IT-00192 Roma
Tel: +39 06 3366 8111

Κύπρος
Zoetis Hellas S.A.
Φραγκοκκλησιάς 7, Μαρούσι
15125, Αττική
Ελλάδα
Τηλ: +30 210 6791900

Latvija
Zoetis Belgium
Mercuriusstraat 20
1930 Zaventem
Beļģija
Tel: +370 610 05088

Suomi/Finland
Zoetis Finland Oy
Bulevardi 21 / SPACES
FI-00180 Helsinki/Helsingfors
Suomi/Finland
Puh/Tel: +358 10 336 7000
laaketurva@zoetis.com

Sverige
Zoetis Animal Health ApS
Øster Alle 48
DK-2100 Köpenhamn
Danmark
Tel: +46 (0) 76 760 0677
adr.scandinavia@zoetis.com

United Kingdom (Northern Ireland)
Zoetis Belgium S.A. (Irish Branch)
2nd Floor, Building 10,
Cherrywood Business Park,
Loughlinstown,
Co. Dublin,
IE – Dublin D18 T3Y1
Tel: +353 (0) 1 256 9800