ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equilis West Nile suspension for injection for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (1 ml) contains:

Active substance:
Flavivirus, strain YF-WN, expressing preM and E proteins genes of West Nile virus, inactivated ≥ 492 AU[1]

[1] Antigenic units determined by ELISA.

Adjuvants:

Iscom-Matrix containing:	
Purified saponin	250 µg
Cholesterol	83 µg
Phosphatidylcholine	42 µg

Excipients:

Qualitative composition of excipients and other constituents
Sodium chloride
Potassium chloride
Disodium hydrogen phosphate dihydrate
Potassium dihydrogen phosphate
Water for injections

Opalescent suspension.

3. CLINICAL INFORMATION

3.1 Target species

Horses.

3.2 Indications for use for each target species

Active immunisation of horses against West Nile virus (WNV) to reduce clinical signs of disease and lesions in the brain and to reduce viraemia.

Onset of immunity: 2 weeks after primary vaccination course of two injections.

Duration of immunity: 1 year.

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:
Not applicable.

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:

Very common (>1 animal / 10 animals treated):	Injection site swelling[1]. Elevated temperature[2].

[1] Max. 3 cm in diameter normally resolving within 1 to 5 days.
[2] An increase of max. 1.5 °C may occur for 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.

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

Intramuscular use.

Vaccination schedule:
Administer one dose (1 ml) by intramuscular injection, according to the following schedule:

- *Primary vaccination:* first injection from 6 months of age onwards, second injection 3 to 5 weeks later.
- *Revaccination:* a yearly booster injection of one dose (1 ml) should be sufficient to achieve a reduction of fever, lesions in the brain and viraemia.

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, distribute, 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.

The vaccine stimulates active immunity against West Nile virus in horses.

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 in a refrigerator (2 °C – 8 °C).
Do not freeze.
Protect from light.

5.4 Nature and composition of immediate packaging

Type I glass vials of 1 ml (1 dose) closed with a halogenobutyl rubber stopper and sealed with an aluminium cap.

Type I glass pre-filled syringes of 1ml (1 dose), containing a plunger with a halogenobutyl end and closed with a halogenobutyl stopper.

Pack sizes:
Cardboard box with 10 glass vials of 1 ml (1 dose).
Plastic box with 10 glass vials of 1 ml (1 dose).
Cardboard box with 5 or 10 pre-filled syringes of 1 ml (1 dose).
Plastic box with 5 or 10 pre-filled syringes of 1 ml (1 dose).

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

Intervet International B.V.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/13/151/001-003

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 06/06/2013.

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 (https://medicines.health.europa.eu/veterinary).

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

BOX
Cardboard box or plastic box with 10 vials of 1 ml, or 5 or 10 pre-filled syringes of 1 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equilis West Nile suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (1 ml) contains:
Flavivirus, strain YF-WN, expressing preM and E proteins genes of West Nile virus, inactivated
≥ 492 AU

3. PACKAGE SIZE

10 vials x 1 dose
5 pre-filled syringes x 1 dose
10 pre-filled syringes x 1 dose

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 in a refrigerator. 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

Intervet International B.V.

14. MARKETING AUTHORISATION NUMBERS

EU/2/13/151/001 (10 vials)
EU/2/13/151/002 (5 pre-filled syringes)
EU/2/13/151/003 (10 pre-filled syringes)

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL
1 ml vial, 1 ml pre-filled syringe

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equilis West Nile 

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Flavivirus, strain YF-WN, expressing West Nile virus antigens, inac.

1 ml (1 dose)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Equilis West Nile suspension for injection for horses

2. Composition

Each dose (1 ml) contains:

Active substance:
Flavivirus, strain YF-WN, expressing preM and E proteins genes of West Nile virus, inactivated
≥ 492 AU[1]

[1] Antigenic units

Adjuvants:

Iscom-Matrix containing:	
Purified saponin	250 µg
Cholesterol	83 µg
Phosphatidylcholine	42 µg

Opalescent suspension.

3. Target species

Horses.

4. Indications for use

Active immunisation of horses against West Nile virus (WNV) to reduce clinical signs of disease and lesions in the brain and to reduce viraemia.

Onset of immunity: 2 weeks after primary vaccination course of two injections.
Duration of immunity: 1 year.

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

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.

Pregnancy and lactation:

Can be used during pregnancy and lactation.

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.

Overdose:
Following the administration of a double dose of vaccine, no adverse reactions other than those described under "Adverse events" section have been observed.

Special restrictions for use and special conditions for use:
Any person intending to manufacture, import, possess, distribute, 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:

Very common (>1 animal / 10 animals treated):	Injection site swelling[1]. Elevated temperature[2].

[1] Max. 3 cm in diameter normally resolving within 1 to 5 days.
[2] An increase of max. 1.5 °C may occur for 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.

Vaccination schedule:
Administer one dose (1 ml) by intramuscular injection, according to the following schedule:

- *Primary vaccination:* first injection from 6 months of age onwards, second injection 3 to 5 weeks later.
- *Revaccination:* a yearly booster injection of one dose (1 ml) should be sufficient to achieve a reduction of fever, lesions in the brain and viraemia.

9. Advice on correct administration

None.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

Store in a refrigerator (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. The expiry date refers to the last day of that month.

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.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/13/151/001-003

Pack sizes:
Cardboard box with 10 glass vials of 1 ml (1 dose).
Plastic box with 10 glass vials of 1 ml (1 dose).
Cardboard box with 5 or 10 pre-filled syringes of 1 ml (1 dose).
Plastic box with 5 or 10 pre-filled syringes of 1 ml (1 dose).

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 (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:
Intervet International B.V., Wim de Körverstraat 35, 5831 AN Boxmeer, The Netherlands

België/Belgique/Belgien
Tél/Tel: + 32 (0)2 370 94 01

Република България
Тел: + 359 28193749

Česká republika
Tel: + 420 233 010 242

Danmark
Tlf: + 45 44 82 42 00

Deutschland
Tel: + 49 (0)8945614100

Eesti
Tel: + 37052196111

Ελλάδα
Τηλ: + 30 210 989 7452

España
Tel: + 34 923 19 03 45

France
Tél: + 33 (0)241228383

Hrvatska
Tel: + 385 1 6611339

Ireland
Tel: + 353 (0) 1 2970220

Ísland
Sími: + 354 535 7000

Italia
Tel: + 39 02 516861

Κύπρος
Τηλ: + 30 210 989 7452

Latvija
Tel: + 37052196111

Lietuva
Tel: + 37052196111

Luxembourg/Luxemburg
Tél/Tel: + 32 (0)2 370 94 01

Magyarország
Tel.: + 36 1 439 4597

Malta
Tel: + 39 02 516861

Nederland
Tel: + 32 (0)2 370 94 01

Norge
Tlf: + 47 55 54 37 35

Österreich
Tel: + 43 (1) 256 87 87

Polska
Tel.: + 48 22 18 32 200

Portugal
Tel: + 351 214 465 700

România
Tel: + 40 21 311 83 11

Slovenija
Tel: + 385 1 6611339

Slovenská republika
Tel: + 420 233 010 242

Suomi/Finland
Puh/Tel: + 358 10 2310 750

Sverige
Tel: + 46 (0)8 522 216 60

United Kingdom (Northern Ireland)
Tel: + 353 (0) 1 2970220

17. Other information

The vaccine stimulates active immunity against West Nile virus in horses.