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 dose of 1 ml contains:

Active substance:

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

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

Adjuvant:
SP oil 4.0% – 5.5% (v/v)

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

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

None.

4.5 Special precautions for use

Special precautions for use in animals

Vaccinate healthy animals only.

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, ingestion or spillage onto skin, seek medical advice immediately and show the package leaflet or label to the physician.

4.6 Adverse reactions (frequency and seriousness)

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 and that are sometimes associated with pain and mild depression were reported in very rare cases. In very rare cases transient hyperthermia may occur for up to 2 days.

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

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

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 Amounts to be administered and administration route

For 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.

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

Pharmacotherapeutic group: Immunologicals for Equidae, inactivated viral vaccines for horses.
ATCvet code: QI05AA10.

The vaccine stimulates active immunity against West Nile virus.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Minimum essential medium (MEM)
Phosphate buffered saline

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf life of the veterinary product as packaged for sale:
pre-filled glass syringe: 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

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 Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
BELGIUM

8. MARKETING AUTHORISATION NUMBERS

EU/2/08/086/004–006

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21/11/2008
Date of last renewal: 12/09/2013

10. DATE OF THE REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

PROHIBITION OF SALE, SUPPLY AND/OR USE

The manufacture, import, possession, sale, supply and/or use of Equip WNV may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation. Any person intending to manufacture, import, possess, sell, supply and use Equip WNV must consult the relevant Member State's competent authority on the current vaccination policies prior to the manufacture, import, possession, sale, supply and/or use.

ANNEX II

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURERS RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. STATEMENT OF THE MRLs

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE AND MANUFACTURERS RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer of the biological active substance:
Zoetis Inc.
2000 Rockford Road,
Charles City, IA 50616
USA

Name and address of the manufacturers responsible for batch release:
Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
BELGIUM

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

According to Article 71 of Directive 2001/82/EC of the European Parliament and of the Council as amended, a Member State may, in accordance with its national legislation, prohibit the manufacture, import, possession, sale, supply and/or use of immunological veterinary medicinal products on the whole or part of its territory if it is established that:

a) The administration of the product to animals will interfere with the implementation of a national programme for the diagnosis, control or eradication of animal diseases, or will cause difficulties in certifying the absence of contamination in live animals or in foodstuffs or other products obtained from treated animals.

b) The disease to which the product is intended to confer immunity is largely absent from the territory in question.

C. STATEMENT OF THE MRLs

The active substance being a principle of biological origin intended to produce active immunity is not within the scope of Regulation (EC) No 470/2009.

The excipients (including adjuvants) listed in section 6.1 of the SPC are either allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required or considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

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. PHARMACEUTICAL FORM

Emulsion for injection

4. PACKAGE SIZE

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

5. TARGET SPECIES

Horses

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read the package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

The import, possession, sale, supply and/or use of this veterinary medicinal product may be prohibited in a Member State on the whole or part of its territory, see package leaflet for further information.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
BELGIUM

16. MARKETING AUTHORISATION NUMBER(S)

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)

17. MANUFACTURER'S 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 injection for horses

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Inactivated West Nile virus, strain VM-2.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 ml

4. ROUTE(S) OF ADMINISTRATION

IM

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
Equip WNV emulsion for injection for horses

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:
Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
BELGIUM

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equip WNV emulsion for injection for horses

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each dose of 1 ml contains:

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

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

Adjuvant:
SP oil 4.0% – 5.5% (v/v).

4. INDICATION(S)

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. ADVERSE REACTIONS

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 and that are sometimes associated with pain and mild depression were reported in very rare cases. In very rare cases transient hyperthermia may occur for up to 2 days.

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

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Horses.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For 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 PERIOD

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 WARNING(S)

Special precautions for use in animals:
Vaccinate healthy animals only.

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, ingestion or spillage onto skin, seek medical advice immediately and show the package leaflet or label to the physician.

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.

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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

15. OTHER INFORMATION

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.

The manufacture, import, possession, sale, supply and/or use of Equip WNV may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation. Any person intending to manufacture, import, possess, sell, supply and use Equip WNV must consult the relevant Member State's competent authority on the current vaccination policies prior to the manufacture, import, possession, sale, supply and/or use.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

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