ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equilis Te suspension for injection for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (1 ml) contains:

Active substance:
Tetanus toxoid 40 Lf [1]

[1] Flocculation equivalents; corresponds with ≥ 30 IU/ml guinea pig serum in the Ph. Eur. potency test

Adjuvants:
Iscom-Matrix containing:
Purified Saponin 375 µg
Cholesterol 125 µg
Phosphatidylcholine 62.5 µg

Excipients:

Qualitative composition of excipients and other constituents
Lactose
Phosphate buffer
Chloride buffer

Clear opalescent suspension.

3. CLINICAL INFORMATION

3.1 Target species

Horses.

3.2 Indications for use for each target species

Active immunisation of horses from 6 months of age against tetanus to prevent mortality.

Onset of immunity: 2 weeks after the primary vaccination course.
Duration of immunity: 17 months after the primary vaccination course,
2 years after the first revaccination.

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:

Foals should not be vaccinated before the age of 6 months, especially when born to mares that were revaccinated in the last two months of gestation, because of possible interference by maternally derived antibodies.

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):	Injection site swelling[1], Injection site pain[2].
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Fever[3], Lethargy[3], Inappetence[3], Hypersensitivity reaction[4].

[1] A diffuse hard or soft swelling (max. diameter 5 cm), regressing within 2 days. A local reaction exceeding 5 cm and possibly persisting longer than 2 days may occur in very rare cases.
[2] Pain at the injection site may result in temporary functional discomfort (stiffness).
[3] Fever, sometimes accompanied by lethargy and inappetence, may occur for 1 day, and up to 3 days in exceptional circumstances.
[4] Including anaphylaxis (sometimes fatal). If such a reaction occurs, appropriate treatment should be administered without delay.

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

Safety and efficacy data are available which demonstrate that this vaccine can be administered on the same day but not mixed with Tetanus Serum from Intervet (see section 3.9).

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the product mentioned above. 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.

Allow the vaccine to reach room temperature before use.

Vaccination schedule:

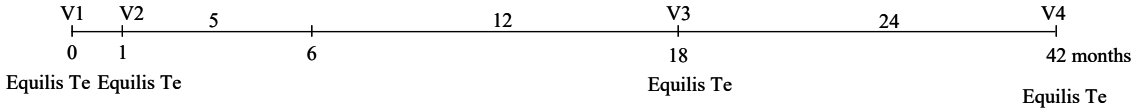
Primary vaccination course

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

- Primary vaccination course: first injection from 6 months of age, second injection 4 weeks later.

Revaccination

The first revaccination is given not later than 17 months after the primary vaccination course. Thereafter a maximum interval of two years is recommended (see scheme).



In case of increased infection risk or insufficient colostrum intake, an additional initial injection can be given at the age of 4 months followed by the full vaccination programme (primary vaccination course at 6 months of age and 4 weeks later).

Concurrent active and passive immunisation (emergency vaccination)

The vaccine can be used together with Tetanus-Serum for treatment of injured horses that have not been immunised against tetanus. In that case, the first dose (V1) of vaccine can be given concurrently with the appropriate prophylactic dose of Tetanus-Serum at a separate injection site, using separate syringes and needles. This will lead to a passive protection against tetanus for at least 21 days after concurrent administration. The second dose of the vaccine (V2) should be administered 4 weeks later. A third vaccination with Equilis Te should be repeated at least four weeks later. Concurrent use of Equilis Te and Tetanus-Serum from Intervet may reduce active immunity against tetanus compared to horses vaccinated with Equilis Te in the absence of tetanus antitoxin serum.

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

Following the administration of a double dose of vaccine, no side effects other than those described under section 3.6 have been observed except for some depression at the day of vaccination.

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

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI05AB03.

To stimulate active immunity against tetanus.

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 syringe of 1 ml (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).
Cardboard box with 10 pre-filled syringes of 1 ml (1 dose) with needles.

Not all pack sizes may be marketed.

5.5 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 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/2/05/055/001-002

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 08/07/2005

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

CARDBOARD BOX with 10 vials
CARDBOARD BOX with 10 pre-filled syringes with needles

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equilis Te suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Tetanus toxoid 40 Lf/ml

3. PACKAGE SIZE

10 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/2/05/055/001 (10 vials)
EU/2/05/055/002 (10 pre-filled syringes)

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL 1 ml vial and 1 ml pre-filled syringe

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equilis Te 

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Tetanus toxoid.

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Equilis Te suspension for injection for horses

2. Composition

Each dose (1 ml) contains:

Active substance:
Tetanus toxoid 40 Lf [1]

[1] Flocculation equivalents; corresponds with ≥ 30 IU/ml guinea pig serum in the Ph. Eur. potency test

Adjuvants:
Iscom Matrix containing:
Purified Saponin 375 µg
Cholesterol 125 µg
Phosphatidylcholine 62.5 µg

Clear opalescent suspension.

3. Target species

Horses.

4. Indications for use

Active immunisation of horses from 6 months of age against tetanus to prevent mortality.

Onset of immunity: 2 weeks after the primary vaccination course.
Duration of immunity: 17 months after the primary vaccination course,
2 years after the first revaccination.

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.

Special precautions for safe use in the target species:
Foals should not be vaccinated before the age of 6 months, especially when born to mares that were revaccinated in the last two months of gestation, because of possible interference by maternally derived antibodies.

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 this package insert 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:
Safety and efficacy data are available which demonstrate that this vaccine can be administered on the same day but not mixed with Tetanus Serum from Intervet (see section: **"**Dosage for each species, routes and method of administration").

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the product mentioned above. 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 side effects other than those described under section "Adverse events" have been observed except for some depression at the day of vaccination.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. Adverse events

Horses:

Rare (1 to 10 animals / 10,000 animals treated):	Injection site swelling[1], Injection site pain[2].
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Fever[3], Lethargy[3], Inappetence[3], Hypersensitivity reaction[4].

[1] A diffuse hard or soft swelling (max. diameter 5 cm), regressing within 2 days. A local reaction exceeding 5 cm and possibly persisting longer than 2 days may occur in very rare cases.
[2] Pain at the injection site can result in temporary functional discomfort (stiffness).
[3] Fever, sometimes accompanied by lethargy and inappetence, may occur for 1 day, and up to 3 days in exceptional circumstances.
[4] Including anaphylaxis (sometimes fatal). If such a reaction occurs, appropriate treatment should be administered without delay.

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}.

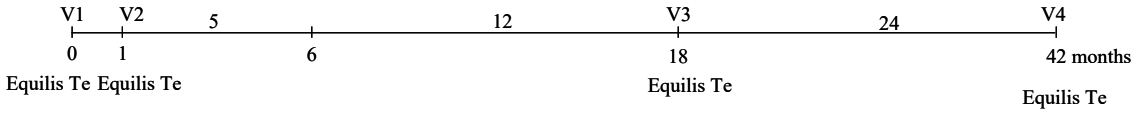
8. Dosage for each species, routes and method of administration

One dose (1ml). Intramuscular use.

Vaccination schedule:

Primary vaccination course
Administer one dose (1ml), by intramuscular injection, according to the following schedule:
- Primary vaccination course: first injection from 6 months of age, second injection 4 weeks later.

Revaccination
The first revaccination is given not later than 17 months after the primary vaccination course.
Thereafter a maximum interval of two years is recommended (see scheme).



In case of increased infection risk or insufficient colostrum intake, an additional initial injection can be given at the age of 4 months followed by the full vaccination programme (primary vaccination course at 6 months of age and 4 weeks later).

Concurrent active and passive immunisation (emergency vaccination)
The vaccine can be used together with Tetanus-Serum for treatment of injured horses that have not been immunised against tetanus. In that case, the first dose (V1) of vaccine can be given concurrently with the appropriate prophylactic dose of Tetanus-Serum at a separate injection site, using separate syringes and needles. This will lead to a passive protection against tetanus for at least 21 days after concurrent administration. The second dose of the vaccine (V2) should be administered 4 weeks later. A third vaccination with Equilis Te should be repeated at least four weeks later. Concurrent use of Equilis Te and Tetanus-Serum from Intervet may reduce active immunity against tetanus compared to horses vaccinated with Equilis Te in the absence of tetanus antitoxin serum.

9. Advice on correct administration

Allow the vaccine to reach room temperature before use.

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/2/05/055/001-002

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

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

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

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Κύπρος
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Latvija
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Polska
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Portugal
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Slovenija
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