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 of 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:
Purified Saponin 375 µg
Cholesterol 125 µg
Phosphatidylcholine 62.5 µg

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Suspension for injection.
Clear opalescent suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Horses

4.2 Indications for use, specifying the 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
24 months after the first revaccination

4.3 Contraindications

None.

4.4 Special warnings for each 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.

4.5 Special precautions for use

Special precautions for use in animals
Only healthy animals should be vaccinated.

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.

4.6 Adverse reactions (frequency and seriousness)

A diffuse hard or soft swelling (max. diameter 5 cm) may rarely occur at the injection site, regressing within 2 days. In very rare cases a local reaction exceeding 5 cm and possibly persisting longer than 2 days may occur. Pain at the injection site can occur in rare cases which may result in temporary functional discomfort (stiffness). In very rare cases, fever, sometimes accompanied by lethargy and inappetence, may occur for 1 day, and up to 3 days in exceptional circumstances.

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).

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation.

4.8 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.

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.

4.9 Amounts to be administered and administration route

Intramuscular use

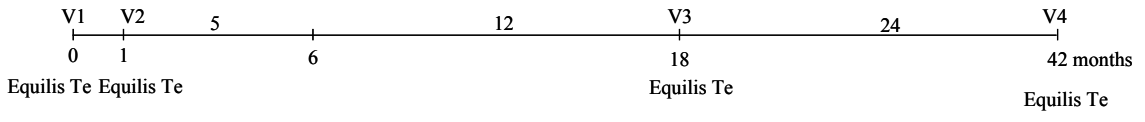
Allow the vaccine to reach room temperature before use.

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Following the administration of a double dose of vaccine, no side effects other than those described under section 4.6 have been observed except for some depression at the day of vaccination.

4.11 Withdrawal period

Zero days.

5. IMMUNOLOGICAL PROPERTIES

To stimulate active immunity against tetanus.

Pharmacotherapeutic group: Inactivated bacterial vaccine.
ATC vet code: QI05AB03

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose
Phosphate buffer
Chloride buffer
Traces of formaldehyde
Purified Saponin
Cholesterol
Phosphatidylcholine

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years

6.4 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).
Protect from light.

Do not freeze.

6.5 Nature and composition of immediate packaging

1 ml suspension in type I glass vial closed with a halogenobutyl rubber stopper and sealed with an aluminium cap.
1 ml suspension in type I glass pre-filled syringe, containing a plunger with a halogenobutyl end and closed with a halogenobutyl stopper.

Package size:
Cardboard box with 10 glass vials.
Cardboard box with 10 pre-filled syringes with needles.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products 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

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/05/055/001-002

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 08/07/2005
Date of last renewal: 10/06/2015

10. DATE OF 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

Not applicable.

ANNEX II

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

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. STATEMENT OF THE MRLs

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

Name and address of the manufacturers of the biological active substance

GSK Vaccines GmbH
Emil-von-Behring-Str. 76
35 041 Marburg
Germany

Name and address of the manufacturer responsible for batch release

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

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) 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

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 for horses

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Tetanus toxoid 40 Lf/ml

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

10 x 1 dose

5. TARGET SPECIES

Horses

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator. Protect from light. Do not freeze.

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

Read package leaflet before use.

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.

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

Intervet International B.V.
NL-5831 AN Boxmeer

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/05/055/001
EU/2/05/055/002

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1 ml vial and 1 ml pre-filled syringe

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equilis Te [*a clear pictogram of a horse*]

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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

1 dose

4. ROUTE(S) OF ADMINISTRATION

IM

5. WITHDRAWAL PERIOD

Withdrawal period: Zero days

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
Equilis Te suspension 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

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equilis Te suspension for injection for horses

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

Each dose of 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:
Purified Saponin 375 µg
Cholesterol 125 µg
Phosphatidylcholine 62.5 µg

A clear opalescent suspension.

4. INDICATION(S)

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
24 months after the first revaccination

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

A diffuse hard or soft swelling (max. diameter 5 cm) may rarely occur at the injection site, regressing within 2 days. In very rare cases a local reaction exceeding 5 cm and possibly persisting longer than 2 days may occur. Pain at the injection site can occur in rare cases which may result in temporary functional discomfort (stiffness). In very rare cases, fever, sometimes accompanied by lethargy and inappetence, may occur for 1 day, and up to 3 days in exceptional circumstances.

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 AND METHOD OF ADMINISTRATION

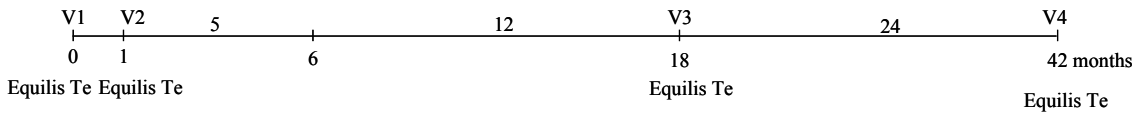
Intramuscular use

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.
Administer 1 ml of vaccine intramuscularly.

10. WITHDRAWAL PERIOD

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the label.

12. SPECIAL WARNING(S)

Special warnings for each 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 for use in animals:
Only healthy animals should be vaccinated.

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 8).

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.

Incompatibilities:
Do not mix with any other veterinary medicinal product.

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

15. OTHER INFORMATION

Package sizes:
Cardboard box with 10 glass vials.
Cardboard box with 10 pre-filled syringes with needles.

Not all pack sizes may be marketed.