

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equilis Prequenza Te suspension for injection for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 1 ml contains:**Active substances:**

Equine influenza virus strains:	
A/equine-2/ South Africa/4/03	50 AU ¹
A/equine-2/ Newmarket/2/93	50 AU
Tetanus toxoid	40 Lf ²

¹ Antigenic units

² Flocculation equivalents; corresponds with ≥ 30 IU/ml guinea pig serum in the Ph.Eur. potency test

Adjuvants:

Iscom-Matrix containing:

Purified Saponin	375 micrograms
Cholesterol	125 micrograms
Phosphatidylcholine	62.5 micrograms

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 equine influenza to reduce clinical signs and virus excretion after infection, and active immunisation against tetanus to prevent mortality.

Influenza

Onset of immunity:	2 weeks after the primary vaccination course
Duration of immunity:	5 months after the primary vaccination course 12 months after the first revaccination

Tetanus

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.

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals

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.

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. Pain at the injection site can occur in rare cases which may result in temporary functional discomfort (stiffness). A local reaction exceeding 5 cm and possibly persisting longer than 2 days may occur in very rare cases. Fever, sometimes accompanied by lethargy and inappetence, may in very rare cases 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 treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, 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 (see section 4.9).

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.

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 (1 ml), strictly intramuscularly, according to the following schedule:

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

Revaccination

Influenza

It is recommended that a single booster dose should only be administered to horses that have already received a primary vaccination course using vaccines that contain the same types of equine influenza virus included in this vaccine. A primary vaccination course may be considered necessary in horses that have not been suitably primed.

The first revaccination (third dose) against equine influenza is given 5 months after the primary vaccination course. This revaccination results in immunity to equine influenza lasting at least 12 months.

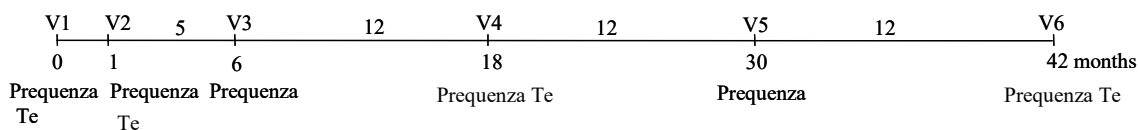
The second revaccination is given 12 months after the first revaccination.

The alternate use, at 12 months interval, of a suitable vaccine against equine influenza, containing the strains A/equine-2/South Africa/4/03 and A/equine-2/Newmarket-2/93, is recommended to maintain immunity levels for the influenza component (see scheme).

Tetanus

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 from Intervet 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 from Intervet 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 Prequenza Te should be repeated at least four weeks later. Concurrent use of Equilis Prequenza Te and Tetanus-Serum from Intervet may reduce active immunity against tetanus compared to horses vaccinated with Equilis Prequenza 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(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for Equidae, inactivated viral and inactivated bacterial vaccines
ATC-vet code: QI05AL01

To stimulate active immunity against Equine influenza and tetanus in horses.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Phosphate buffer, traces of thiomersal, traces of formaldehyde

6.2 Major 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 (at 2 °C – 8 °C).

Do not freeze.

Protect from light.

6.5 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 1 ml (1 dose), containing a plunger with a halogenobutyl end and closed with a halogenobutyl stopper.

Package sizes:

Cardboard box with 10 glass vials of 1 ml (1 dose).

Cardboard box(es) with 1, 5 or 10 pre-filled syringes of 1 ml (1 dose) 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 products 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/2/05/057/001-004

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 08 July 2005

Date of last renewal: 27 July 2010

10. DATE OF REVISION OF THE TEXT

{MM/YYYY}

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 SUBSTANCES 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 SUBSTANCES AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer of the biological active substances

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

Merck Sharp & Dohme Animal Health, S.L.
Poligono Ind. El Montalvo I
C/Zepelin 6, Parcela 38
37008 Carbajosa de la Sagrada
Salamanca
Spain

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

Name and address of the manufacturer responsible for batch release

Intervet International BV
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 in 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 1, 5, or 10 pre-filled syringes

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equilis Prequenza Te suspension for injection for horses

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each dose of 1 ml contains:A/equine-2/ South Africa/4/03 50 AU

A/equine-2/Newmarket/2/93 50 AU

Tetanus toxoid 40 Lf.

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

10 x1 dose

1 dose in a pre-filled syringe

5 x 1 dose in pre-filled syringes

10 x 1 dose in pre-filled syringes

5. TARGET SPECIES

Horses

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s): zero days

9. SPECIAL WARNING(S), IF NECESSARY

Read package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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

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

Disposal: read 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.

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.
Wim de Körverstraat 35
NL-5831 AN Boxmeer

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/05/057/001 (10 vials)
EU/2/05/057/002 (10 pre-filled syringes)
EU/2/05/057/003 (1 pre-filled syringe)
EU/2/05/057/004 (5 pre-filled syringe)

17. MANUFACTURER'S 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 Prequenza Te



2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Two equine influenza virus strains and tetanus toxoid.

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

1 dose

4. ROUTE(S) OF ADMINISTRATION

IM

5. WITHDRAWAL PERIOD(S)

Withdrawal period(s): 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:

Equilis Prequenza 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 Prequenza Te suspension for injection for horses

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

Each dose of 1 ml contains:

Active substances

Equine influenza virus strains:
A/equine-2/ South Africa/4/03 50 AU¹
A/equine-2/ Newmarket/2/93 50 AU

Tetanus toxoid 40 Lf²

¹ Antigenic ELISA units

² Flocculation equivalents; corresponds with ≥ 30 IU/ml guinea pig serum in the Ph.Eur. potency test

Adjuvant

Iscom Matrix containing:

Purified saponin 375 micrograms
Cholesterol 125 micrograms
Phosphatidylcholine 62.5 micrograms

Clear opalescent suspension.

4. INDICATION(S)

Active immunisation of horses from 6 months of age against equine influenza to reduce clinical signs and virus excretion after infection, and active immunisation against tetanus to prevent mortality.

Influenza

Onset of immunity: 2 weeks after the primary vaccination course
Duration of immunity: 5 months after the primary vaccination course
 12 months after the first revaccination

Tetanus

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. Pain at the injection site can occur in rare cases which may result in temporary functional discomfort (stiffness). A local reaction exceeding 5 cm and possibly persisting longer than 2 days may occur in very rare cases. Fever, sometimes accompanied by lethargy and inappetence, may in very rare cases 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 treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Horses



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

1 ml. Intramuscular use.

Vaccination schedule:

Primary vaccination course

Administer one dose (1 ml) strictly intramuscularly according to the following schedule:

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

Revaccination

Influenza

It is recommended that a single booster dose should only be administered to horses that have already received a primary vaccination course using vaccines that contain the same types of equine influenza virus included in this vaccine. A primary vaccination course may be considered necessary in horses that have not been suitably primed.

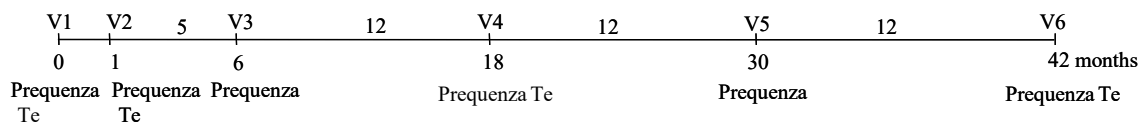
The first revaccination (third dose) against equine influenza is given 5 months after the primary vaccination course. This revaccination results in immunity to equine influenza lasting at least 12 months.

The second revaccination is given 12 months after the first revaccination.

The alternate use, at 12 months interval, of a suitable vaccine against equine influenza, containing the strains A/equine-2/South Africa/4/03 and A/equine-2/Newmarket-2/93, is recommended to maintain immunity levels for the influenza component (see scheme).

Tetanus

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 from Intervet 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 from Intervet 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 Prequenza Te should be repeated at least four weeks later. Concurrent use of Equilis Prequenza Te and Tetanus-Serum from Intervet may reduce active immunity against tetanus compared to horses vaccinated with Equilis Prequenza Te in the absence of tetanus antitoxin serum.

9. ADVICE ON CORRECT ADMINISTRATION

Allow the vaccine to reach room temperature before use.

10. WITHDRAWAL PERIOD(S)

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 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.

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 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: Dosage for each species, route(s) 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 (symptoms, emergency procedures, antidotes):
Following the administration of a double dose of vaccine, no side-effects other than those described under section 6. Adverse reactions, have been observed except for some depression at the day of vaccination.

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

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

<DD/MM/YYYY>

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

Cardboard box with 10 glass vials of 1 ml (1 dose).
Cardboard box with 1, 5 or 10 pre-filled syringes of 1 ml (1 dose) with needles.

Not all pack sizes may be marketed.