

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equilis Prequenza suspension for injection for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (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

¹ Antigenic units

Adjuvants:

Iscom-Matrix containing:

Purified Saponin	375 µg
Cholesterol	125 µg
Phosphatidylcholine	62.5 µg

Excipients:

Qualitative composition of excipients and other constituents
Phosphate 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 equine influenza to reduce clinical signs and virus excretion after infection.

Onset of immunity:	2 weeks after the primary vaccination course.
Duration of immunity:	5 months after the primary vaccination course, 1 year 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

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.

Allow the vaccine to reach room temperature before use.

Vaccination schedule:

Primary vaccination course

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

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

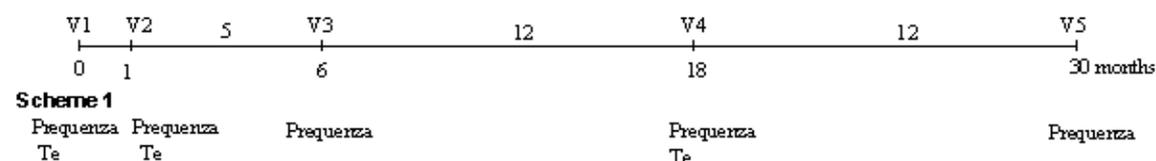
Revaccination

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) 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).



Scheme 2

Prequenza Prequenza Prequenza Prequenza Prequenza

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).

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

Official control authority batch release is required for this product.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI05AA01.

To stimulate active immunity against Equine influenza 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 (at 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 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 1, 5 or 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/2/05/056/001-004

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 1, 5, or 10 pre-filled syringes

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equilis Prequenza suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 1 ml contains:
A/equine-2/ South Africa/4/03 50 AU
A/equine-2/Newmarket/2/93 50 AU

3. PACKAGE SIZE

10 x 1 dose
1 dose in a pre-filled syringe
5 x 1 dose in pre-filled syringes
10 x 1 dose in pre-filled syringes

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 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/2/05/056/001 (10 vials)
EU/2/05/056/002 (10 pre-filled syringes)
EU/2/05/056/003 (1 pre-filled syringe)
EU/2/05/056/004 (5 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 Prequenza



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Two equine influenza virus strains.

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Equilis Prequenza suspension for injection for horses

2. Composition

Each dose (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

¹ Antigenic ELISA units

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 equine influenza to reduce clinical signs and virus excretion after infection.

Onset of immunity:	2 weeks after the primary vaccination course.
Duration of immunity:	5 months after the primary vaccination course, 1 year 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:

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 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 (1 ml). Intramuscular use.

Vaccination schedule:

Primary vaccination course

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

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

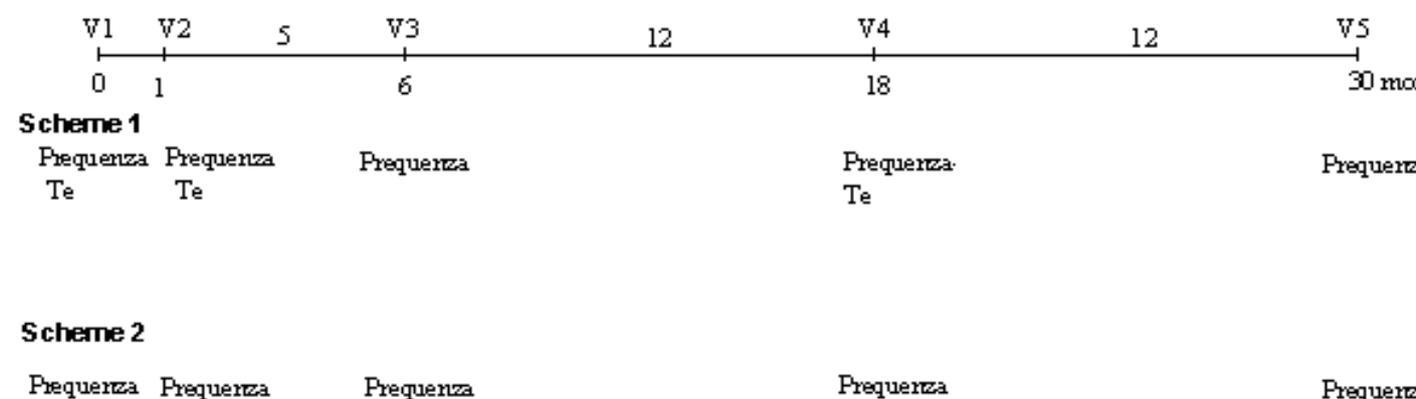
Revaccination

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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).



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).

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/2/05/056/001-004

Pack sizes:

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.

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

Lietuva

Tel: + 37052196111

Република България

Тел: + 359 28193749

Luxembourg/Luxemburg

Tél/Tel: + 32 (0)2 370 94 01

Česká republika

Tel: + 420 233 010 242

Magyarország

Tel.: + 36 1 439 4597

Danmark

Tlf: + 45 44 82 42 00

Malta

Tel: + 39 02 516861

Deutschland

Tel: + 49 (0)8945614100

Nederland

Tel: + 32 (0)2 370 94 01

Eesti

Tel: + 37052196111

Norge

Tlf: + 47 55 54 37 35

Ελλάδα

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España

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Hrvatska

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Ireland

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Sími: + 354 535 7000

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Latvija

Tel: + 37052196111

Österreich

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Polska

Tel.: + 48 22 18 32 200

Portugal

Tel: + 351 214 465 700

România

Tel: + 40 21 311 83 11

Slovenija

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