

## **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

**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. 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 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**

MSD Animal Health UK Ltd.

**14. MARKETING AUTHORISATION NUMBERS**

Vm 01708/5031

**15. BATCH NUMBER**

Lot {number}

**16. SPECIAL WARNING(S), IF NECESSARY**

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

Disposal: Read package leaflet.

**18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE**

**POM-V** Veterinary medicinal product subject to prescription.

**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. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)**

Two equine influenza virus strains and tetanus toxoid.  
A/equine-2/South Africa/4/03 50 AU, A/equine-2/Newmarket/2/93 50 AU, Tetanus toxoid 40 Lf per dose

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}

**5. ROUTE(S) OF ADMINISTRATION**

IM use.

**6. THE WORDS "FOR ANIMAL TREATMENT ONLY"**

For animal treatment only.

## PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

### 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equilis Prequenza Te 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 <sup>1</sup>
A/equine-2/Newmarket/2/93	50 AU
Tetanus toxoid	40 Lf <sup>2</sup>

<sup>1</sup> Antigenic ELISA units

<sup>2</sup> Flocculation equivalents; corresponds with  $\geq 30$  IU/ml guinea pig serum in the Ph.Eur. potency test

#### Adjuvants:

Iscom Matrix containing:

Purified saponin	375 $\mu$ g
Cholesterol	125 $\mu$ g
Phosphatidylcholine	62.5 $\mu$ g

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, 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.  
1 year 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.  
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.

### Special precaution for the protection of the environment:

Not applicable.

### 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 MSD Animal Health (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 "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 <sup>1</sup> , Injection site pain <sup>2</sup> .
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Fever <sup>3</sup> , Lethargy <sup>3</sup> , Inappetence <sup>3</sup> , Hypersensitivity reaction <sup>4</sup> .

<sup>1</sup> 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.

<sup>2</sup> Pain at the injection site may result in temporary functional discomfort (stiffness).

<sup>3</sup> Fever, sometimes accompanied by lethargy and inappetence, may occur for 1 day, and up to 3 days in exceptional circumstances.

<sup>4</sup> 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:

E-mail: [adverse.events@vmd.gov.uk](mailto:adverse.events@vmd.gov.uk)

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

## 8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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*

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.

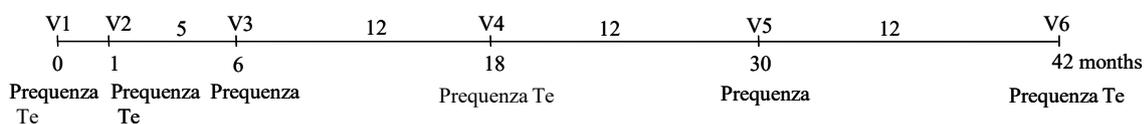
The second revaccination is given 12 months after the first revaccination.

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

## **13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS**

Veterinary medicinal product subject to prescription.

## **14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES**

Vm 01708/5031

### 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**

September 2023

Find more product information by searching for the 'Product Information Database' or 'PID' on [www.gov.uk](http://www.gov.uk).

## 16. CONTACT DETAILS

Marketing authorisation holder and contact details to report suspected adverse reactions:

MSD Animal Health UK Ltd.  
Walton Manor, Walton  
Milton Keynes  
Buckinghamshire  
MK7 7AJ, UK  
Tel: + 44 (0)1908 685685

Manufacturer responsible for batch release:

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

## 17. OTHER INFORMATION

POM-V Veterinary medicinal product subject to prescription.

For animal treatment only.

Approved 19 February 2024

A handwritten signature in black ink, appearing to read "A. Hunter.", is positioned below the approval date.