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 AND OTHER SUBSTANCES

Tetanus toxoid 40 Lf/ml

3. PACKAGE SIZE

10 x 1 dose

4. TARGET SPECIES

Horses

5. INDICATION(S)

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 NUMBER

Vm 01708/5034

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
1 ml vial and 1 ml pre-filled syringe

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equilis Te

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

Tetanus toxoid 40 Lf/ml

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 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.

Special precautions 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 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:
E-mail: adverse.events@vmd.gov.uk
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

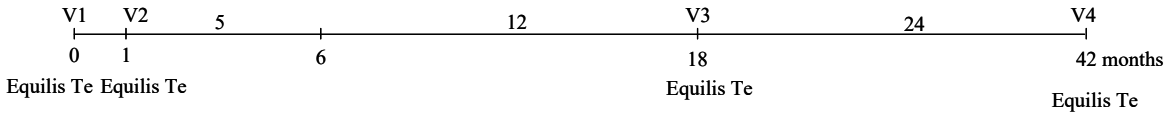
8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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
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 MSD Animal Health 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.
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 01708/5034

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.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

July 2023

Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder:
MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

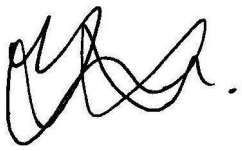
Manufacturer responsible for batch release:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

Contact details to report suspected adverse reactions:
MSD Animal Health UK Ltd.
Tel: + 44 (0)1908 685685

17. OTHER INFORMATION

For animal treatment only.

POM-V
Veterinary medicinal product subject to prescription.



Approved: 19 February 2024