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 (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

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.
2 years after the first revaccination.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals:

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.

4.6 Adverse reactions (frequency and seriousness)

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 also section 16 of the package leaflet for contact details.

4.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

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 MSD Animal Health (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 Amount(s) to be administered and administration route

Intramuscular use.

Allow the vaccine to reach room temperature before use.

Vaccination schedule:

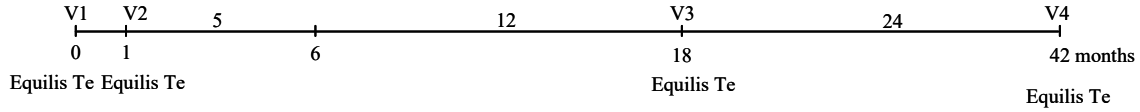
Primary vaccination course

Administer one dose (1 ml), 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.

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: Inactivated bacterial vaccine.

ATCvet code: QI05AB03

To stimulate active immunity against tetanus.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose
Phosphate buffer
Chloride buffer

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 (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.

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.

6.6 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.
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

MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ
United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 01708/5034

9. DATE OF FIRST AUTHORISATION

08 July 2005

10. DATE OF REVISION OF THE TEXT

November 2023

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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

Approved 27 November 2023