SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tetanus Antitoxin Behring Solution for Injection for Horses, Sheep and Dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml contains:

Active substances:
Protein from horses ≤ 170 mg
with tetanus antitoxin ≥ 1,000 IU

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Phenol	3.7 mg – 5 mg
Sodium chloride	8.5 mg
Water for injections	

Clear solution.

3. CLINICAL INFORMATION

3.1 Target species

Horses, sheep and dogs.

3.2 Indications for use for each target species

This veterinary medicinal product is intended for prophylactic use in horses, sheep and dogs to reduce the risk of tetanus infection, as a result of accidental injury or as a preoperative precaution.

This veterinary medicinal product is intended for therapeutic use in horses and dogs to enhance recovery rates in animals showing clinical signs of tetanus, when combined with other treatments.

Onset of immunity: After subcutaneous and intramuscular injection: 2 days after administration.
After intravenous or intramuscular injection to horses: 1 – 4 hours.
After subarachnoidal injection: straight after application.

Duration of immunity: 2 – 3 weeks.
The duration of effective antibody titres has not been investigated in the central nervous system. The intravenous and subarachnoidal application routes are recommended for therapeutic use of this veterinary medicinal product in horses only.

3.3 Contraindications

Administration to cats is contraindicated. Cats are unable to metabolise the preservative phenol as rapidly as other species due to the absence of a specific enzyme.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
After repeated administration at longer intervals sensitisation may occur, leading to hypersensitivity reactions/anaphylactic shock. Administering repeat doses at longer intervals is therefore not recommended. Especially if a (repeated) intravenous application is intended in heterologous animals a biological pre-testing (1 ml, subcutaneous, 30 – 40 minutes observation) should be performed.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
None.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Horses, dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site swelling[1] Hyperthermia[2] Hypersensitivity reaction[3]

[1] Transient
[2] Transient. May occur on the day of application and the day after.
[3] Especially after repeated administration. Especially heterologous animals are susceptible.

Sheep:

Rare (1 to 10 animals / 10,000 animals treated):	Hyperthermia[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site swelling[2] Hypersensitivity reaction[3]

[1] Transient. May occur on the day of application and the day after.
[2] Transient
[3] Especially after repeated administration. Especially heterologous animals are susceptible.

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 its local representative 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

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. However, with regard to use in horses, on the basis of experience from field use in mares and from published data employing the administration of a different tetanus hyperimmune serum in pregnant mares it is concluded that it is unlikely to cause any reaction other than that described in section 3.6.

3.8 Interaction with other medicinal products and other forms of interaction

Safety and efficacy data are available which demonstrate that this immunological veterinary medicinal product can be administered on the same day but not mixed with Equilis Te and Equilis Prequenza Te (for proper use, refer to the package leaflets). No information is available on the safety and efficacy of this immunological veterinary medicinal product when used with any other veterinary medicinal product except the products mentioned above. A decision to use this immunological veterinary medicinal product 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

I. Dosage and method of administration in horses
I.a Prophylaxis:
Method of administration:
Subcutaneous or intramuscular injection.
Dosage for preoperative treatment or after injury:

Horse	7,500 – 10,000 IU = 7.5 – 10 ml
Foal with body weight up to 100 kg	3,000 IU = 3.0 ml

If the operation wound or the injury has not improved after 10 – 14 days the serum application has to be repeated (see section 3.4).

<u>Simultaneous with vaccination</u>
Subcutaneous or intramuscular injection.
This veterinary medicinal product and vaccines* against tetanus are to be applied at different parts of the body.

*Equilis Prequenza Te and Equilis Te. For proper use please refer to the relevant package leaflets.

Dosage see 'prophylaxis'.

I.b Therapeutic:
Method of administration:
Preferably intravenous injection, otherwise subcutaneous or intramuscular injection. To supply the central nervous system with antitoxin the administration of this veterinary medicinal product into the subarachnoid space is recommended (see section 3.6).

Dosage:

Horse	20,000 – 50,000 IU = 20 – 50 ml
Foal with body weight up to 100 kg	30,000 IU = 30 ml

The given doses should be applied in an as early as possible stage of the disease. A repeated administration on the two following days can be useful.

II. Dosage and method of administration in sheep
Method of administration:
Subcutaneous application.

The dosage for preoperative treatment or after injury should contain:

Sheep (subcutaneous)	3,000 IU = 3.0 ml
Lamb (subcutaneous)	1,500 IU = 1.5 ml

III. Dosage and method of administration in dogs
Method of administration:
Subcutaneous or intramuscular application.

a. The dosage for preoperative treatment or after injury should contain:

Dog depending on the body weight (80 IU/kg)	Min 500 – max 2,500 IU = 0.5 – 2.5 ml

b. The therapeutical dosage should contain:

Dog depending on the body weight (1,000 IU/kg)	Min 10,000 – max 20,000 IU = 10 – 20 ml

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Do not administer more than the dose indicated to horses or dogs. In sheep the administration of an overdose of 6 ml/6,000 IU may result in an increase in body temperature of up to 2 °C and local reactions, but no ulceration or abscess formation should be observed.

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

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI04AM02, QI05AM01, QI07AM

To provide passive immunity against tetanus infection.

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: 42 months.
Once broached use within 10 hours and keep stored at 2 °C – 8 °C.

5.3 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).
Do not freeze.
Protect from light.

5.4 Nature and composition of immediate packaging

Cardboard box with 1 x 50 ml moulded type I glass bottle, closed with a type I chlorobutyl rubber stopper and an aluminium crimp cap.

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

Vm 06376/4140

8. DATE OF FIRST AUTHORISATION

14 October 2005

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

November 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

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

Gavin Hall
Approved: 22 February 2026