1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tetanus Antitoxin Behring solution for injection for horses, sheep and dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
Equine serum protein containing a minimum of 1 000 IU* *Clostridium tetani* antitoxin per ml.

* IU: Specific neutralising activity for tetanus toxin contained in a stated amount of the International Standard which consists of a quantity of dried immune horse serum.

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Phenol	≤ 5.0 mg
Sodium chloride	
Water for injection	

Clear solution.

3. CLINICAL INFORMATION

3.1 Target species

Horses, sheep, dogs.

3.2 Indications for use for each target species

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.

For therapeutic use in horses and dogs to increase the recovery rates in animals suffering from clinical tetanus.

Onset of passive immunity:
- Subcutaneous and intramuscular injection: within 2 days*.
- Intravenous injection: within 3 hours*.
- Subarachnoidal injection: immediately after application**.

* Maximum serological titres are reached.
**Effective titres in the central nervous system are reached.

Duration of passive immunity:
- Subcutaneous, intramuscular and intravenous injection: 2 – 3 weeks; once maximum serological titres are reached the titre slowly decreases with time.
- Subarachnoidal injection: has not been established.

Intravenous and subarachnoidal administration routes are recommended in horses only.

3.3 Contraindications

Do not use in cats. 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:

Not applicable.

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, dogs:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Elevated temperature[1] Hypersensitivity reaction (e.g. Anaphylaxis)[2] Injection site swelling[3]

[1] Transient. Not exceeding 2 °C. May occur on the day of application and the day after.
[2] Especially after repeated administration. Heterologous animals are especially susceptible. Shock therapy must be initiated immediately.
[3] Transient. After administration of large volumes associated with therapeutic doses.

Sheep:

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

[1] Transient. Not exceeding 2 °C. May occur on the day of application and the day after.
[2] Especially after repeated administration. Heterologous animals are especially susceptible. Shock therapy must be initiated immediately.
[3] Transient. After administration of large volumes associated with therapeutic doses.

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:
Can be used during pregnancy.

3.8 Interaction with other medicinal products and other forms of interaction

Horses:
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 or Equilis Prequenza Te. The immunological veterinary medicinal products should be given at different sites. For details on concurrent use please refer to the product information of Equilis Te or Equilis Prequenza Te. Within the product information of Equilis Te and Equilis Prequenza Te this immunological veterinary medicinal product is referred to as 'Tetanus Serum from Intervet'.

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.

Sheep and dogs:
No information is available on the safety and efficacy of this immunological veterinary medicinal product when used with any other veterinary medicinal product. 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

Intravenous (**i.v.**), subcutaneous (**s.c.**), intramuscular (**i.m.**) or subarachnoidal use.

Administer the veterinary medicinal product observing aseptic precautions. Syringes and needles should be sterile. No alcohol or disinfectant should be used for the sterilisation procedure.

Prophylactic application for pre-operation treatment or after injury:

Category	**Route of administration**	**IU/kg bodyweight**
Horse > 100kg	**s.c.** or **i.m.**	20
Foal ≤ 100 kg		30
Sheep > 15 kg	**s.c.**	60*
Lambs ≤ 15 kg		100
Dogs > 15 kg	**i.m.**	80
Dogs/puppies ≤ 15 kg		100**

* The overall application dose in sheep should not be higher than 6 ml (= 6 000 IU/animal)
** Dogs/puppies ≤ 5 kg receive a general dose of 0.5 ml (= 500 IU/animal)

A repeat dose of the veterinary medicinal product should be given to dogs and horses if the wound or injury has not healed within 10 – 14 days. The safety of the repeated administration in sheep has not been determined.

Therapeutic application:
The intravenous and subarachnoidal application routes are recommended for therapeutic use of this veterinary medicinal product in horses only.

Category	**Route of administration**	**IU/kg bodyweight**	**Maximum dose/animal**
Horse > 100kg	Preferably **i.v.**, otherwise **s.c.** or **i.m.**	100	Max 53 000 IU = 53 ml
Foal ≤ 100 kg		300	Max 33 000 IU = 33 ml
Dogs	**i.m.**	1 000	Max 20 000 IU = 20 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.
Large volumes of serum given intravenously should be administered slowly.
Large intramuscular dosages should be divided into several different injection sites.

Administration into the subarachnoid space in horses:
Very good results in the therapeutic treatment of tetanus in horses were observed when the veterinary medicinal product was administered into the subarachnoid space to supply the central nervous system with antitoxin. Adult horses should receive maximum 50 000 IU and foals ≤ 100 kg should receive maximum 30 000 IU into the subarachnoid space. Additionally, 3 000 IU should be given subcutaneously.

Prior to the administration of the corresponding amount of the veterinary medicinal product through the cisterna magna into the subarachnoid space, the horse has to be generally anaesthetised, and the same amount of the cerebrospinal fluid should be removed by means of a suitable syringe. As a security measure the horse should be intubated.

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

The administration of an overdose is unlikely to cause any reaction other than described in section 3.6.

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

Horses:
Meat and offal: Zero days.
Milk: Zero days.

Sheep:
Meat and offal: Zero days.
Milk: Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code : QI04AM02, QI05AM01, QI07AM

This veterinary medicinal product is a purified blended antiserum derived from horses which provides 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.
Shelf life after first opening the immediate packaging: 10 hours.

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

Carton box with one 50 ml multidose glass bottle (Glass Type I, Ph.Eur.), closed with a chlorobutyl rubber stopper (Ph.Eur. Type I) and sealed with an aluminium crimp cap.

Pack sizes:
Cardboard box with 1 x 50 ml glass bottle.

5.5 Special precautions for the disposal of unused veterinary medicinal products 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 Ireland Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA 10996/150/001

8. DATE OF FIRST AUTHORISATION

09/04/2003

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

21/11/2025

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).