SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tetanus Antitoxin Behring

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Constituents	**per 1 ml**
protein from horses	max. 170 mg
with antibodies against tetanus	1000 IU
Excipient	
Phenol	min. 3.7 mg
	max. 5.0 mg

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Tetanus Antitoxin Behring is a purified antiserum derived from horses, presented as a clear antitoxin solution.

4. CLINICAL PARTICULARS

4.1 Target species

Horse, sheep and dog.

4.2 Indications for use

Tetanus Antitoxin Behring 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.
After subcutaneous and intramuscular injection of Tetanus Antitoxin Behring, maximum serological titres can be expected approximately 2 days after administration. The titres slowly decrease with time, but the protective effect lasts for between 2 and 3 weeks.

Tetanus Antitoxin Behring 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
After intravenous or intramuscular injection to horses, serological titres associated with protection can be reached within one to four hours.

After subarachnoidal injection effective titres in the central nervous system are reached straight after application. 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 Tetanus Antitoxin Behring in horses only.

4.3 Contraindications

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

4.4 Special warnings for each 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 Tetanus Antitoxin Behring, subcutaneous, 30 - 40 minutes observation) should be performed.

4.5 Special precautions for use, including special precautions to be taken by the person administering the medicinal product to animals.

Special precautions for use in animals

None.

Special precautions to be taken by the person administering the medicinal product to animals

None.

4.6 Adverse reactions (frequency and seriousness)

A transient local swelling may occur after vaccination. A transient rise in body temperature may occasionally occur on the day of application and the day after. In very rare cases, especially after repeated administration, hypersensitivity reactions may occur. Especially heterologous animals are susceptible (see 4.4).
It has been concluded from studies that the product is unlikely to exacerbate the disease when it is administered to horses affected with clinical tetanus, with doses of 20,000 to 50,000 IU, administered by the intramuscular, subcutaneous or intravenous routes, if necessary repeated at intervals over the space of a few days, or by injection into the subarachnoid space.

4.7 Use during pregnancy, lactation or lay

The safe use of Tetanus Antitoxin Behring during pregnancy and lactation has not specifically been assessed. 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 4.6.

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 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 vaccine when used with any other veterinary medicinal product except the products 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 Amounts to be administered and administration route

I. Dosage and method of administration in horses
I.a Prophylaxis:
Method of administration:
Subcutaneous or intramuscular application.
Dosage for pre-operation 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 4.4).

Simultaneous with vaccination
Application: subcutaneously or intramuscularly.
Tetanus Antitoxin Behring and vaccines* against tetanus are to be applied at different parts of the body. Dosage see 'prophylaxis'.

I.b Therapeutic:
Method of administration:
Application preferably intravenously, otherwise subcutaneously or intramuscularly.
To supply the central nervous system with antitoxin the administration of Tetanus Antitoxin Behring into the subarachnoid space is recommended (see also point 4.6).

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

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 pre-operation 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 pre-operation treatment or after injury should contain:

Dog (intramuscular) 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 (intramusculat) depending on the body weight (1000 IU/kg)	Min 10,000 – max 20,000 IU	=	10 – 20 ml

4.10 Overdose (symptoms, emergency procedures, antidotes) (if necessary)

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 2ºC and local reactions, but no ulceration or abscess formation should be observed.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

To provide passive immunity against tetanus infection.
ATC-vet code: QI04AM02, QI05AM01, QI07AM

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Phenol, salts

6.2 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: 42 months
Shelf life after first opening of the immediate packaging: Broached multidose containers should be used within one working day (10 hours) and kept stored at 2 ºC - 8 ºC.

6.4 Special precautions for storage

Store at 2 ºC - 8 ºC. Protect from light. Do not freeze.

6.5 Nature and composition of immediate packaging

Cardboard box with one injection bottles made of moulded glass of glass type I according to Ph.Eur. sealed with a chlorobutyl rubber stopper of rubber type I according to Ph.Eur. and an aluminium crimp cap.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 06376/4140

9. DATE OF FIRST AUTHORISATION

14 October 2005

10. DATE OF REVISION OF THE TEXT

February 2025

Gavin Hall

Approved: 25 February 2025