Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Tetanus Antitoxin Behring

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance (s):Per ml

Equine serum protein containing a minimum of 1000 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.

Excipient (s):

Preservative:
Phenol Maximum 5.0 mg
For a full list of excipients see Section 6.1

3 PHARMACEUTICAL FORM

Solution for injection

4 CLINICAL PARTICULARS

4.1 Target Species

Horses, sheep, dogs of all ages

4.2 Indications for use, specifying the target species

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.

Tetanus Antitoxin Behring is intended for therapeutic use in horses and dogs to increase the recovery rates in animals suffering from clinical tetanus.

After subcutaneous and intramuscular injection of Tetanus Antitoxin Behring, maximum serological titres are reached within 2 days. The titre slowly decreases with time, but the protective effect lasts for between 2 and 3 weeks.

After intravenous injection, maximum serological titres are reached within three hours and decrease slowly at a similar rate to that following subcutaneous or intramuscular injection.

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

None.

4.5 Special precautions for use

Special precautions for use in animals

None.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
In the case of accidental self-injection, seek medical advice immediately and show the package leaflet or label to the physician.

4.6 Adverse reactions (frequency and seriousness)

A transient rise in body temperature not exceeding 2°C may occasionally occur on the day of application and the day after. In very rare cases (<1/1000) especially after repeated administration anaphylactoid reactions can occur. Heterologous animals are especially susceptible. In case of a hypersensitivity reaction, shock therapy must be initiated immediately.

After administration of large volumes associated with therapeutic doses transient local swellings at the injection sites might occur.

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy.

4.8 Interaction with other medicinal products and other forms of interactions

Sheep and dogs
No information is available on the compatibility of Tetanus Antitoxin Behring with any other immunological product. Therefore the safety and efficacy of this product when used with any other (either when used on the same day or at different times) has not been demonstrated.

Horses
In horses prophylactic doses of Tetanus Antitoxin Behring may be administered subcutaneously at the same time as Tetanus Toxoid Concentrated (Intervet) but at separate injection sites. A second dose of Tetanus Toxoid Concentrated (Intervet) should be given 4 weeks later.

4.9 Amounts to be administered and administration route

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 (= 6000 I.U./animals)
** Dogs/puppies ≤ 5 kg receive a general dose of 0.5 ml (= 500 I.U./animal)

A repeat dose of Tetanus Antitoxin Behring 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:

Category	Route of administration	IU/kg bodyweight	Maximum dose/animal
Horse > 100kg	Preferably i.v., otherwise s.c. or i.m.	100	Max 53000 IU = 53 ml
Foal ≤ 100 kg		300	Max 33000 IU = 33 ml
Dogs	i.m.	1000	Max 20000 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.

Application in horses
Administration into the subarachnoid space in horses:
Very good results in the therapeutic treatment of tetanus in horses wereobserved when Tetanus Antitoxin Behring 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 Tetanus Antitoxin Behring through the cisterna magna into the subarachnoid space, the horse has to be generally anaesthetised, and the same amount of the cerebro spinal fluid should be removed by means of a suitable syringe. As a security measure the horse should be intubated.

Administer Tetanus Antitoxin Behring observing aseptic precautions. Syringes and needles should be sterile. No alcohol or disinfectant should be used for the sterilisation procedure.

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

The administration of an overdose is unlikely to cause any reaction other than described in section 4.6.

4.11 Withdrawal period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATCvet code: QI04AM02, QI05AM01, QI07AM
Tetanus Antitoxin Behring is a purified blended antiserum derived from horses which provides passive immunity against tetanus infection.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Phenol
Sodium chloride
Water for injection

6.2 Major incompatibilities

Do not mix with any other medicinal product.

6.3 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

6.4 Special precautions for storage

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

6.5 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.

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

Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Limited
Magna Drive
Magna Business Park, Citywest Road
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10996/150/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 09 April 2003
Date of last renewal: 08 April 2008

10 DATE OF REVISION OF THE TEXT

February 2020