PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> <AND> <THE IMMEDIATE PACKAGE> {CARTON BOX}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tetanus Antitoxin Behring

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Content per ml:

Purified equine antiserum containing max. 170 mg protein from horses with 1000 IU antibodies against tetanus. Phenol - 5.0 mg (preservative).

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 ml (50,000 I.U.)

5. TARGET SPECIES

Horses, sheep and dogs.

6. INDICATION(S)

[Optional. In case of space restriction and if the indication is clear from the name of the product, the indication should not be repeated]

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read package leaflet before use.

8. WITHDRAWAL PERIOD

Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

<User Warnings>

10. EXPIRY DATE

Expiry end of:

11. SPECIAL STORAGE CONDITIONS

Store at 2 °C - 8 °C. Protect from light.

Do not freeze.

Once broached use within 10 hours.

Keep container in the outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

For animal treatment only.

POM-V

To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA holder

MSD Animal Health UK Ltd.

Walton Manor

Walton

Milton Keynes

MK7 7AJ

Distributor in Northern Ireland

Intervet Ireland Ltd.

Magna Drive

Magna Business Park

Citywest Road

Dublin 24

16. MARKETING AUTHORISATION NUMBER

Vm 01708/4506

17. MANUFACTURER’S BATCH NUMBER

Batch:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {LABEL}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tetanus Antitoxin Behring

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Protein from horses: max. 170 mg/ml with antibodies against tetanus: 1000 IU/ml

Phenol ≤ 5.0 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

50 ml (50,000 I.U.)

4. ROUTE(S) OF ADMINISTRATION

Solution for injection

5. WITHDRAWAL PERIOD

Zero days.

6. BATCH NUMBER

Batch:

7. EXPIRY DATE

Expiry end of:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only. Keep out of the sight and reach of children.

[Include information under these headings as it appears in the SPC]

PACKAGE LEAFLET FOR:

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder

MSD Animal Health UK Ltd.

Walton Manor

Walton

Milton Keynes

Buckinghamshire

MK7 7AJ

Manufacturer for the batch release:

Intervet International B.V.

Wim de Körverstraat 35

5831 AN

Boxmeer

The Netherland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tetanus Antitoxin Behring

Solution for injection.

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Protein from horses	max. 170 mg/ml
with antibodies against tetanus	1000 IU/ml

Phenol (preservative) 3.7 - 5.0 mg/ml

4. INDICATION(S)

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.

5. 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

6. ADVERSE REACTIONS

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 “special warnings”). 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.If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Horses, sheep and dogs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

I. Dosage and method of administration in horses

I.a Prophylaxis:

Method of administration: Subcutaneous or intramuscular injection.

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 “Special warnings”).

Simultaneous with vaccination

Method of administration: subcutaneous or intramuscular injection.

Tetanus Antitoxin Behring and vaccines* against tetanus are to be applied at different parts of the body.

Dosage see ‘prophylaxis’.

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

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 Tetanus Antitoxin Behring into the subarachnoid space is recommended (see section “Adverse Reactions”).
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 injection

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

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

III. Dosage and method of administration in dogs

Method of administration: Subcutaneous or intramuscular injection.

The dosage for pre-operation treatment or after injury should contain:

Dog (IM) 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 (IM) depending on the body weight (1000 IU/kg)	Min 10,000 – max 20,000 IU = 0.5 – 2.5 ml

9. ADVICE ON CORRECT ADMINISTRATION

See section 8.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store at 2 ºC - 8 ºC. Protect from light.

Do not freeze. Keep container in the outer carton.

Do not use after the expiry date stated on the label and carton.

Shelf-life after first opening the container 10 hours

12. SPECIAL WARNING(S)

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 subcutaneously, 30 - 40 minutes observation) should be performed.

Special precautions for use in animals

None.

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

None.

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 “Adverse reactions”.

Interactions

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.Do not mix with any other veterinary medicinal product.

Administration of an overdose

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

June 2021

<15. OTHER INFORMATION>

For animal treatment only.

Pack size

1 x 50 ml bottle

MA number

Vm 01708/4506

Legal category

POM-V

To be supplied only on veterinary prescription.

Distributor in Northern Ireland

Intervet Ireland Ltd.

Magna Drive

Magna Business Park

Citywest Road

Dublin 24

Approved: 09/06/21