

IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2) REGULATIONS 2007

(S.I. No. 786 of 2007)

VPA: **10996/151/001**

Case No: 7006085

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

Intervet Ireland Limited

Magna Drive, Magna Business Park, Dublin 24, Ireland

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Tetanus Toxoid Concentrated

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

The authorisation, unless revoked, shall continue in force from **23/11/2009**.

Signed on behalf of the Irish Medicines Board

A person authorised in that behalf by the said Board.

(NOTE: This authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Tetanus Toxoid Concentrated

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:	1 dose (1 ml)
Purified, concentrated tetanus toxoid	27 Lf units*

* 27 Lf units resulting in a minimum potency of 30 IU/ml when tested in guinea pigs according to Ph.Eur.

Adjuvant:	
Aluminium hydroxide	3.0 mg

Excipients:
For a full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Suspension for injection

4 CLINICAL PARTICULARS

4.1 Target Species

Horses, cattle, sheep, pigs, cats and dogs.

4.2 Indications for use, specifying the target species

For the active immunisation of horses, cattle, sheep, pigs, cats and dogs to reduce mortality and clinical signs of the disease caused by infection with *Clostridium tetani*.

Onset of immunity: 10-14 days after the basic immunisation (two doses).

Duration of immunity:

Cattle, sheep, pigs, cats and dogs: One year

Horses: Two years

The first booster immunisation (third dose) leads to a rapid increase of the antitoxin titre.

For concurrent administration with Tetanus Antitoxin Behring to injured horses that have not been vaccinated or are not completely immunised against tetanus, to prevent mortality and reduce clinical signs of the disease caused by infection with *Clostridium tetani*.

For the active immunisation of pregnant mares, cows, ewes, sows, queens and bitches in order to provide passive immunity to the progeny against mortality and clinical disease caused by infection with *Clostridium tetani*.

Booster vaccination of pregnant animals may result in passive immunity of their offspring lasting for about 4-6 months in horses, 3-5 months in cattle and 1.5-2.5 months in sheep, pigs, cats and dogs.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Only vaccinate healthy animals.

In any group of animals a small number of individuals may fail to respond to vaccination as a result of immunological incompetence or for some other reasons.

4.5 Special precautions for use

Special precautions for use in animals

None.

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

In the case of accidental self-injection, wash the area with water, seek medical advice and show the package leaflet or the label to the physician.

Other precautions

None

4.6 Adverse reactions (frequency and seriousness)

Adverse reactions are rare (1/40,000). A transient swelling at the injection site up to 3 cm in diameter, lasting for 2 to 3 days, may occur. A slight increase in body temperature, up to 1.5°C, may be observed the day following vaccination.

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy.

4.8 Interaction with other medicinal products and other forms of interaction

Horses

Safety and/or efficacy data are available which demonstrate that this vaccine can be administered the same day but not mixed with Tetanus Antitoxin Behring, Equilis Prequenza and Equilis Resequin. At each occasion, Tetanus Toxoid Concentrated may be used concurrently with only one of these products. These products should be administered at a separate injection site, using a separate syringe plus needle. Concurrent use with Tetanus Antitoxin Behring is indicated only for prophylactic purposes in injured horses that have not been vaccinated or are not completely immunised against tetanus.

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 decided on a case by case basis.

Cattle, sheep, pigs, cats and dogs

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product in cattle, sheep, pigs, cats and dogs.

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

For horses, cattle, sheep, pigs, cats and dogs:

Dose: 1 ml

Administration: Intramuscular injection

Shake the vial before use.

Syringes and needles should be from gamma irradiated packs or freshly sterilised by boiling for 20 minutes, but no alcohol or other disinfectants should be used for this procedure.

HORSES

Basic vaccination

All horses not previously vaccinated should be vaccinated twice at an interval of 4-8 weeks. Foals can be vaccinated from 2 months of age. In foals from mares vaccinated during pregnancy (see below) maternally derived immunity may interfere with vaccination. These animals should not be vaccinated before 4-6 months of age.

Revaccination

A third dose should be given about 12 months after the basic immunisation.

Thereafter booster vaccinations can be given at 2 years interval.

Active immunisation of animals during pregnancy

A booster vaccination of pregnant mares 4-8 weeks prior to foaling leads, via the colostrum, to passive immunisation of the foals for their first 4-6 months of life.

Particularly when vaccinating pregnant animals, stress should be avoided.

Foals from fully vaccinated mares should take up colostrum within the first 24 hours of life.

Concurrent active and passive immunisation

For effective immunisation of injured horses that have not been vaccinated or are not completely immunised against tetanus, animals should receive two doses with an interval of 4-8 weeks. At the first vaccination Tetanus Antitoxin Behring is administered simultaneously but at a separate injection site, using separate syringes and needles.

Animals not vaccinated earlier with Tetanus Toxoid concentrated should receive a further dose after approximately 12 months with a re-vaccination dose being given every 2 years thereafter.

CATTLE, SHEEP, PIGS, CATS AND DOGS

Although Tetanus Toxoid Concentrated is not normally used for routine vaccination in these animal species and its use is often restricted to situations where a tetanus threat is suspected or has been experienced, the following general guidance can be given:

Basic vaccination

All animals not previously vaccinated should be vaccinated twice at an interval of 4-8 weeks. Calves can be vaccinated from 2 months of age, lambs and piglets from 1 month of age and kittens and pups from 2 months of age.

In young animals born to vaccinated dams that were vaccinated during pregnancy (see below) maternally derived immunity may interfere with vaccination at the minimum recommended age. In these instances, calves should not be vaccinated before 4 months of age, lambs and piglets not before 2 months of age. At the minimum age (2 months) recommended for vaccinating kittens and pups, interference by maternally derived immunity is not to be expected.

Revaccination

If further vaccinations are found necessary, booster vaccinations must be given at intervals of about 12 months.

Active immunisation of animals during pregnancy

A booster vaccination of pregnant animals 4-6 weeks prior to parturition leads, via the colostrum, to passive immunisation of the young for their first 3-5 months (cattle) or 1.5-2.5 months (sheep, pigs, cats and dogs) of life. Particularly when vaccinating pregnant animals, stress should be avoided.

Animals born to fully vaccinated dams should take up colostrum within the first 24-36 hours of life.

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

The vaccine has been shown to be safe when administered at twice the recommended dose. Other effects than those described in section 4.6 are not to be expected.

4.11 Withdrawal Period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC-Vet code: QI02AB, QI04AB, QI05AB, QI06AB, QI07AB, QI09AB

To stimulate active immunity against tetanus.

To stimulate active immunity in order to provide passive immunity to the progeny against tetanus.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Water for injections

6.2 Incompatibilities

Do not mix with any other medicinal product.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 4 years.

6.4 Special precautions for storage

Store in a refrigerator (2 °C- 8 °C)
Keep the container in the outer carton in order to protect from light.

6.5 Nature and composition of immediate packaging

Carton with 10 glass vials (type I Ph.Eur.) containing 1 ml with a rubber stopper and aluminium cap.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road
Dublin 24

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/151/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

27th March 2009

10 DATE OF REVISION OF THE TEXT

23rd November 2009