

# Summary of Product Characteristics

## 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Duvaxyn T

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

### Qualitative composition

Tetanus vaccine for veterinary use.

### Quantitative composition

Active Substances;	Per 1.0 ml dose
Tetanus toxoid (purified);	$\geq 30$ IU*

### Adjuvant:

Aluminium phosphate	3.5 mg
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### Excipients:

For a full list of excipients, see Section 6.1

\*Mean potency determined by enzyme linked immunosorbent assay (ELISA) compared to a reference antiserum. Ph. Eur. 0697.

## 3 PHARMACEUTICAL FORM

Suspension for injection.

## 4 CLINICAL PARTICULARS

### 4.1 Target Species

Ponies and horses from the age of five months.

### 4.2 Indications for use, specifying the target species

For the active immunisation of horses and ponies to prevent tetanus infection.

Protective antitoxin antibody titres have been shown to be present within two weeks of completion of the second dose of the primary vaccination course.

Following administration of the second dose of the primary vaccination course, protective antitoxin antibody titres last at least 1 year. After each subsequent booster vaccination, antitoxin antibody titres last at least 2 years.

### 4.3 Contraindications

Do not vaccinate unhealthy animals.

#### **4.4 Special warnings for each target species**

Maternally derived antibody (MDA) can interfere with the development of active immunity. Please refer to section 4.9 for advice on vaccination in the presence of MDA.

Animals that have received tetanus antiserum at a therapeutic dosage should not be vaccinated until an interval of at least 4 weeks has elapsed.

#### **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/ingestion/spillage onto skin, seek medical advice immediately and show the package insert or label to the physician.

#### **4.6 Adverse reactions (frequency and seriousness)**

Following administration of Duvaxyn T, commonly observed reactions include palpable swelling at the injection site lasting not more than one day and mild, transient hyperthermia appearing within a few days of vaccination and resolving within a day. Hypersensitivity reactions to the vaccine may occur. In the event of an allergic reaction, immediate treatment should be given with a soluble glucocorticoid intravenously (e.g. dexamethasone sodium phosphate), adrenaline intramuscularly or antihistamine intramuscularly.

#### **4.7 Use during pregnancy, lactation or lay**

The vaccine can be safely administered to mares in foal during the 2<sup>nd</sup> and 3<sup>rd</sup> trimester and to lactating mares, provided they have been previously vaccinated against tetanus. However, the risks connected with any treatment of a pregnant animal are undiminished.

#### **4.8 Interaction with other medicinal products and other forms of interaction**

No information is available on the safety and efficacy of the concurrent use of this vaccine with any other except Duvaxyn IE Plus or Duvaxyn EHV 1,4. It is therefore recommended that no other vaccines than these should be administered within 14 days before or after vaccination with the product.

## 4.9 Amounts to be administered and administration route

One 1.0 ml dose per horse to be administered by deep intramuscular injection.

Shake well before use.

Syringes and needles should not have been sterilised chemically or be above ambient temperature.  
The skin at the site chosen for injection should not be disinfected prior to vaccination using chemical disinfectants.

### Vaccination Schedule

#### - Primary vaccination:

A single dose of Duvaxyn T should be administered from five months of age followed by a second dose of Duvaxyn T after an interval of 4-6 weeks.

Primary vaccination of foals born to mares highly immunised against tetanus (i.e. vaccinated two or more times a year or within the last trimester of pregnancy) should be delayed until the age of 6 months, as such foals may have high levels of maternally-derived antibody against tetanus toxoid that could interfere with successful immunisation.

In cases of increased risk of tetanus in the young foal, especially when colostrum intake has been inadequate, an additional vaccination may be given from three months of age. Such foals should be shown to have no or very low titres of IgG using a suitable test before proceeding with early vaccination. The full primary course of vaccination should still be given from five months of age.

#### - Booster vaccination:

The first booster vaccination should be administered 1 year after completion of the primary vaccination course and at intervals of 2 years thereafter.

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

Administration of a double dose does not alter the severity of the reaction seen after administration of the recommended dose (see Section 4.6).

## 4.11 Withdrawal Period(s)

Zero days.

## 5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

To stimulate active immunity against *Clostridium tetani* toxin.

ATCVet Code: QI05AB03

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Aluminium phosphate  
Potassium dihydrogen phosphate,  
Disodium hydrogen phosphate,  
Sodium chloride  
Water for injections.

### 6.2 Incompatibilities

Do not mix any with other veterinary medicinal product.

### **6.3 Shelf-life**

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.  
Use entire contents when first opened.

### **6.4 Special precautions for storage**

Store and transport at 2°C - 8°C.  
Protect from light.  
Do not freeze.

### **6.5 Nature and composition of immediate packaging**

Hydrolytic Type I (Ph.Eur.) glass vial, 1 dose per vial.  
Butyl rubber stopper (Ph.Eur.) and aluminium seals.  
Duvaxyn T is supplied in plastic trays containing 2, 10 single dose vials.

Not all pack sizes may be marketed.

### **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 product should be disposed of in accordance with local requirements.

## **7 MARKETING AUTHORISATION HOLDER**

Elanco Animal Health  
Eli Lilly and Company Limited  
Priestly Road  
Basingstoke  
RG24 9NL  
United Kingdom

## **8 MARKETING AUTHORISATION NUMBER(S)**

VPA 10047/022/001

## **9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 20th April 2007  
Date of last renewal: 20th April 2012

## **10 DATE OF REVISION OF THE TEXT**