SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Duvaxyn T

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

	Per 1 ml dose
Active substance:	
Purified Tetanus toxoid	≥ 30 IU*

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

Adjuvant:	
Aluminium phosphate	3.5 mg

Excipient(s):
None giving rise to safety concerns.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.

4. CLINICAL PARTICULARS

4.1 Target species

Ponies and horses from the age of three months.

4.2 Indications for use, specifying the target species

For the active immunisation of horses and ponies against tetanus. Protective antitoxin antibody titres are detected within two weeks of the second vaccination and last for 1 year. After the third vaccination and subsequent biannual booster vaccinations, protective titres last two years.

4.3 Contraindications

Do not use in unhealthy animals.

4.4 Special warnings

The skin at the site chosen for injection should not be disinfected prior to vaccination using chemical disinfectants.
Maternally derived antibody (MDA) can interfere with the development of active immunity. Where it is likely that recent field infection or vaccination of the dam has stimulated a high antibody titre and consequently a high level of MDA, the timing of the vaccination programme should be planned accordingly.
In any animal population there will be a small number of individuals which fail to respond fully to vaccination. Successful vaccination depends upon correct storage and administration of the vaccine and the animal's ability to respond. Immune competence can be influenced by genetic factors, intercurrent infection, age, nutritional status, concurrent drug therapy, stress, etc.
Animals that have received the corresponding antiserum at a therapeutic dosage or immunosuppressive drugs (e.g. glucocorticoids) should not be vaccinated until an interval of at least 4 weeks has elapsed.

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

i. Special precautions for use in animals

Avoid stress in the animals around the time of vaccination.

ii. 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, a small, palpable injection-site reaction may result in approximately 2% of vaccinated animals. No information on microscopic features of the injection site reactions is available.
Transient elevation of body temperature may be seen within few days of vaccination in approximately 2% of vaccinated animals.
While extremely rare, 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

Duvaxyn T may only be used in pregnant or lactating mares which have been given a primary vaccination course prior to pregnancy. 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

Safety and efficacy data are available which demonstrate that this vaccine can be administered on the same day but not mixed with Duvaxyn IE Plus or Duvaxyn EHV 1,4. 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

One 1.0 ml dose per horse to be administered by deep intramuscular injection.
Syringes and needles should not have been sterilised chemically or be above ambient temperature.
Vaccination Schedule
Primary course:
A single dose of Duvaxyn T should be administered from three months of age followed by a second injection of Duvaxyn T after an interval of 4-6 weeks and a third injection 1 year after that.
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.
Boosting Immunity:
Booster vaccinations should be administered at two year intervals.

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.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

To stimulate active immunity against *Clostridium tetani* toxin.

ATCVet code: QI05AB03

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Potassium dihydrogen phosphate
Disodium hydrogen phosphate
Water for injections

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: 2 years.
Use entire contents when first opened.

6.4. Special precautions for storage

Store and transport at 2-8°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 stoppers (Ph.Eur.) and aluminium seals.

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

Elanco Animal Health
Eli Lilly & Company Limited
Lilly House
Priestly Road
Basingstoke
Hampshire
RG24 9NL

8. MARKETING AUTHORISATION NUMBER(S)

Vm 00006/4124

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26-Oct-2005
Renewal of the authorisation: 26-Oct-2010

10. DATE OF REVISION OF THE TEXT

Date: December 2011

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.