A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Cardboard Box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Duvaxyn® T

2. STATEMENT OF ACTIVE SUBSTANCES

Adjuvanted equine tetanus vaccine (toxoid) ≥ 30 IU / dose

3. PHARMACEUTICAL FORM

Suspension for intramuscular injection.

4. PACKAGE SIZE

10 x 1 dose.

5. TARGET SPECIES

For active immunisation of horses and ponies from the age of three months against tetanus.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular injection.

8. WITHDRAWAL PERIOD(S)

Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

For use: see package leaflet

10. EXPIRY DATE

Exp.:

11. SPECIAL STORAGE CONDITIONS

Use entire contents when first opened.
Store and transport refrigerated (2ºC - 8ºC).
Protect from light.
Do not freeze.

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

To be supplied only on veterinary prescription.

UK

POM-V

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Elanco Animal Health
Eli Lilly and Company Ltd
Priestley Road
Basingstoke
Hampshire
RG24 9NL

16. MARKETING AUTHORISATION NUMBER(S)

Vm 00006/4124

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Duvaxyn® T

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Adjuvanted equine tetanus vaccine (toxoid) ≥ 30 IU

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

1 dose.

4. ROUTE(S) OF ADMINISTRATION

For intramuscular injection.

5. WITHDRAWAL PERIOD(S)

Zero days.

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

Exp.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

Store at + 2ºC to + 8ºC.
Do not freeze.
Protect from light.

UK
POM-V

Vm 00006/4124

Elanco Animal Health
Eli Lilly and Company Ltd
Lilly House

Priestley Road
Basingstoke
Hampshire
RG24 9NL

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Duvaxyn® T

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

MARKETING AUTHORISATION HOLDER
Elanco Animal Health, Eli Lilly and Company Ltd,
Lilly House, Priestley Road, Basingstoke, Hampshire, RG24 9NL, United Kingdom

MANUFACTURER RESPONSIBLE FOR BATCH RELEASE
Elanco Animal Health Ireland,
Finisklin Industrial Estate, Sligo,
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Duvaxyn T
Suspension for injection.

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

Purified Tetanus toxoid, ≥ 30 IU* per 1 ml dose.
* Mean potency determined by enzyme linked immunosorbant assay (ELISA) compared to a reference antiserum. Ph Eur. 0697.

4. INDICATION(S)

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.

5. CONTRAINDICATIONS

Do not use in unhealthy animals.
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.
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. Do not mix with any other veterinary medicinal product.

6. ADVERSE REACTIONS

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 reaction is available. Transient elevation of body temperature may be seen within a 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.

7. TARGET SPECIES

Ponies and horses from the age of three months.

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

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.

9. ADVICE ON CORRECT ADMINISTRATION

Syringes and needles should not have been sterilised chemically or be above ambient temperature.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Store and transport 2 - 8ºC.
Protect from light.
Do not freeze.
Use entire contents when first opened.

12. SPECIAL WARNING(S)

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.

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

April 2014.

15. OTHER INFORMATION>

For Animal Treatment Only.

ATC Vet Code: Q105AB03

PACKAGE QUANTITIES
Packs of 2 and 10 single dose vials.
Not all pack sizes may be marketed.

Prescription only medicine – Veterinarian
To be supplied only on veterinary prescription.

UK
POM-V

Vm 00006/4124

Approved: 03/05/2017