

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Duvaxyn IE-T Plus

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Combined equine influenza vaccine (inactivated) and tetanus vaccine for veterinary use.

Active Substances:

Per 1.5 ml dose

Inactivated equine influenza virus, strains:

A/equi-1/Prague/56

15 - 18 µg HA*

A/equi-2/Suffolk/89 (European type)

15 - 18 µg HA*

A/equi-2/Newmarket/1/93 (American type)

15 - 18 µg HA*

Tetanus Toxoid

18 Lf (RP ≥1.0)**

*Haemagglutinin

** Mean potency relative to a reference vaccine of potency > 150 IU / dose.

Adjuvants:

Per 1.5 ml dose

Carbopol 934P

4 mg

Aluminium hydroxide

2.2 mg

Excipient(s):

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 five months.

4.2 Indications for use, specifying the target species

Active immunisation of horses and ponies from 5 months of age against equine influenza of H7N7 and H3N8 types (European and American strains), including the South Africa/4/03 and A/equi-2/Richmond/1/07 strains, to reduce clinical signs and virus excretion after infection, and active immunisation against tetanus to prevent mortality.

Onset of immunity has been demonstrated by virulent challenge for equine influenza strains South Africa 4/03, Richmond 1/07 and Sussex/89, and by serology for vaccine strains Prague/56, Newmarket 1/93 and Suffolk 89. Duration of immunity has been demonstrated by virulent challenge for equine influenza strain Sussex/89 and by serology for all other strains.

Influenza

Onset of immunity: 2 weeks after administration of the 2nd dose
Duration of immunity: 6 months after administration of the 2nd dose
12 months after administration of the 3rd dose and subsequent annual booster injections.

Tetanus

Onset of immunity: 2 weeks after administration of the 2nd dose
Duration of immunity: 6 months after administration of the 2nd dose
24 months after administration of the 3rd dose and subsequent annual booster injections (IE, UK only).

4.3 Contraindications

Do not vaccinate unhealthy animals.

4.4 Special Warnings

It is recommended to vaccinate all horses on the premises according to the recommended schedule.

Maternally derived antibodies (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.

In any animal population there will be a small number of individuals, which fail to respond fully to vaccination.

4.5 Special precautions for use

- 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)

The occurrence of adverse reactions after the first and second doses is low. After the third and subsequent doses, the incidence of adverse reactions, particularly local reactions, increases.

Very commonly these reactions include visible swellings measuring less than 5 cm in diameter lasting for up to 1 day and mild, transient hyperthermia lasting up to 4 days. Common reactions include palpable, transient swellings and large, possibly painful, swellings which resolve within weeks and stiffness of the neck evident at between 2 to 4 days after vaccination. In rare occasions, abscessation may be observed. No information on microscopic features of the injection site reactions is available.

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

Safe for use in pregnant mares in second to third trimester which have been vaccinated against both influenza and tetanus before pregnancy.

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 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 product 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 1.5 ml dose per horse to be administered by deep intramuscular injection. Shake well before use.

Vaccination Schedule

Primary vaccination:

A single dose of Duvaxyn IE-T Plus should be administered from the age of 5 months followed by a second dose of Duvaxyn IE-T Plus after an interval of 4-6 weeks and a third dose 6 months later. Primary vaccination of foals born to mares highly immunised against equine influenza or 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 equine influenza virus and tetanus toxoid that could interfere with successful immunisation.

In cases of increased risk of equine influenza or 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:

Administer a single dose of vaccine annually, beginning with Duvaxyn IE Plus and alternating thereafter with Duvaxyn IE-T Plus.

In enzootic or epizootic situations, especially where the causative strain of equine influenza has not been identified, young horses in a yard or crowded situation may be particularly at risk and an additional six month booster with Duvaxyn IE Plus may be given in order to further enhance the immune response prior to the commencement of the annual booster programme.

It is recommended that Duvaxyn IE-T Plus should not be used as a booster vaccine in horses previously vaccinated with another manufacturer's vaccine nor should another manufacturer's vaccine be used as a booster vaccine in horses previously vaccinated with Duvaxyn IE-T Plus unless the other manufacturer's vaccine comprises the same equine influenza strains as Duvaxyn IE-T Plus.

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. IMMUNOLOGICAL PROPERTIES

To stimulate active immunity against equine influenza virus and *Clostridium tetani* toxin.

ATCVet Code: QI05AL01

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carbopol 934P
Aluminium hydroxide
Potassium dihydrogen phosphate,
Disodium phosphate dihydrate,
Sodium dihydrogen phosphate dihydrate,
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

6.4. Special precautions for storage

Store and transport refrigerated (2°C - 8°C).

Protect from light.

Do not freeze.

6.5 Nature and composition of immediate packaging

Type I glass vial (Ph.Eur.) with Type I butyl rubber stopper (Ph.Eur.) and aluminium crimp cap. One 1.5 ml dose per vial.

Vials are supplied in cardboard boxes containing 2, 10 or 50 vials.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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)

VPA 10047/024/001

Vm 00006/4127

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation

Ireland: 20-Apr-2001

UK: 26-Oct-2005

Date of renewal of the authorisation

UK/Ireland: 26 October 2010

10. DATE OF REVISION OF THE TEXT

Date: September 2012

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

Approved by:

A handwritten signature in purple ink, consisting of a stylized 'A' followed by a horizontal line.

20/11/2012