ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Cardboard Box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Duvaxyn® IE Plus

2. STATEMENT OF ACTIVE SUBSTANCES

Adjuvanted equine influenza.

Inactivated equine influenza virus, strains per 1 ml dose: 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 and Carbopol 934P as adjuvant.

3. PHARMACEUTICAL FORM

Suspension for intramuscular injection.

4. PACKAGE SIZE

10 x 1 dose

5. TARGET SPECIES

Ponies and horses from the age of five months.

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

Read the package leaflet before use.

10. EXPIRY DATE

Exp.:

11. SPECIAL STORAGE CONDITIONS

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

Ireland
POM

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
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 00006/4125

VPA 10047/023/001

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® IE Plus

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Adjuvanted equine influenza (inactivated).

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.

To be supplied only on veterinary prescription.

UK

POM-V

Ireland

POM

Vm 00006/4125

VPA 10047/023/001

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Duvaxyn® IE Plus

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 IE Plus.
Suspension for injection.

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

Inactivated equine influenza virus, strains per 1 ml dose:
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* and Carbopol 934P as adjuvant.

4. INDICATION(S)

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.

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.

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.

5. CONTRAINDICATIONS

Do not vaccinate unhealthy animals.

6. ADVERSE REACTIONS

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.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary practitioner.

7. TARGET SPECIES

Ponies and horses from the age of five months.

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

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

Primary vaccination:
A single dose of Duvaxyn IE Plus should be administered from the age of 5 months followed by a second dose of Duvaxyn IE 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 (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 that could interfere with successful immunisation.
In cases of increased risk of equine influenza 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.
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 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 Plus unless the other manufacturer's vaccine comprises the same equine influenza strains as Duvaxyn IE Plus.

9. ADVICE ON CORRECT ADMINISTRATION

Shake well before use.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Store and transport refrigerated (2ºC - 8ºC).
Protect from light.
Do not freeze.
Do not use after the expiry date stated on the label.

12. SPECIAL WARNING(S)

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 on dosage recommendations for advice on vaccination in the presence of MDA.

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

Duvaxyn IE Plus is safe for use in pregnant mares in the second and third trimester, which have been vaccinated against influenza before pregnancy.

Avoid stress in the animals around the time of vaccination.

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 and Duvaxyn T. 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.

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.

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

December 2012.

15. OTHER INFORMATION>

2, 10 or 50 x 1 dose vials. Not all pack sizes may be marketed.

To be supplied only on veterinary prescription.

UK
POM-V

Ireland
POM

Vm 00006/4125

VPA 10047/023/001

Approved: 03/05/2017