ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ProteqFlu-Te suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose of 1 ml contains:

Active substances:
Influenza A/eq/Ohio/03 [H_3N_8] recombinant Canarypox virus (vCP2242) ..... ⩾ 5.3 log10 $FAID_{50}$*
Influenza A/eq/Richmond/1/07 [H_3N_8] recombinant Canarypox virus (vCP3011)⩾ 5.3 log10 $FAID_{50}$*
Clostridium tetani toxoid ..... ⩾ 30 IU**

* vCP content checked by global $FAID_{50}$ (fluorescent assay infectious dose 50 %) and qPCR ratio between vCP.
** antitoxic antibody titre induced after repeated vaccination in guinea pig sera according to Ph. Eur.

Adjuvant:
Carbomer..... 4 mg

Excipients:

Qualitative composition of excipients and other constituents
Sodium chloride
Disodium hydrogen orthophosphate
Monopotassium phosphate anhydrous
Water for injections

Homogeneous opalescent suspension

3. CLINICAL INFORMATION

3.1 Target species

Horses

3.2 Indications for use for each target species

Active immunisation of horses of 4 months of age or older against equine influenza to reduce clinical signs and virus excretion after infection, and against tetanus to prevent mortality.
Onset of immunity: 2 weeks after primary vaccination course.
Duration of immunity induced by the vaccination scheme:
- 5 months after the primary vaccination course;
- after the primary vaccination course and the booster injection 5 months later: 1 year with regard to equine influenza and 2 years with regard to tetanus.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Horses:

Rare (1 to 10 animals / 10,000 animals treated):	Injection site swelling[1], increased skin temperature, muscle stiffness, injection site pain Elevated temperature[2]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site abscess Apathy, decreased appetite[3] Hypersensitivity reaction[4]

[1]transient, usually regresses within 4 days; in rare occasions swelling can reach a diameter up to 15-20 cm, with duration up to 2–3 weeks that may require symptomatic treatment.
[2]max. 1.5 °C, for 1 day, exceptionally 2 days.
[3]the day after vaccination.
[4]which may require appropriate symptomatic treatment.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See also the last section of the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation.

3.8 Interactions 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 Boehringer Ingelheim's inactivated vaccine against rabies.

The vaccines should be given at different sites.

3.9 Administration routes and dosage

For intramuscular use.
For the administration of the vaccine, use sterile and antiseptic-free and/or disinfectant-free material.
Shake the vaccine gently before use.

Administer one dose (1 ml), by intramuscular injection, preferably in the neck region, according to the following schedule:
- primary vaccination course with ProteqFlu-Te: first injection from 5–6 months of age, second injection 4-6 weeks later.
- Revaccination:

- 5 months after primary vaccination course with ProteqFlu-Te.
- Followed by:
  - against tetanus: injection of 1 dose at an interval of maximum 2 years with ProteqFlu-Te.
  - against equine influenza: injection of 1 dose every year, alternatively with ProteqFlu or ProteqFlu-Te, respecting an interval of maximum 2 years for the tetanus component.

In case of increased infection risk or insufficient colostrum intake, an additional initial injection of ProteqFlu-Te can be given at the age of 4 months followed by the full vaccination programme (primary vaccination course at 5–6 months of age and 4–6 weeks later followed by revaccination).

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Following the administration of overdoses of vaccine, no adverse events other than those described under section 3.6 have been observed.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Official control authority batch release is required for this product.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI05AI01.

The vaccine stimulates active immunity against equine influenza and tetanus.

The vaccine strains vCP2242 and vCP3011 are recombinant canarypox viruses expressing the haemagglutinin *HA* gene from the equine influenza virus strains A/eq/Ohio/03 (American strain, Florida sublineage clade 1) and A/eq/Richmond/1/07 (American strain, Florida sublineage clade2), respectively. After inoculation, the viruses do not multiply in the horse but express the protective proteins. As a consequence, these components induce immunity against equine influenza virus (H_3N_8).

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months.
Shelf life after first opening the immediate packaging: use immediately.

5.3 Special precautions for storage

Store and transport refrigerated (2 °C - 8 °C).
Do not freeze.
Protect from light.

5.4 Nature and composition of immediate packaging

Type I glass vial.
Butyl elastomer closure and aluminium cap.

Box of 10 vials of 1 dose.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/03/038/005

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 06/03/2003

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database.

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

10 vials of 1 dose

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ProteqFlu-Te suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

One dose of 1 ml contains:

Influenza A/eq/Ohio/03 [H_3N_8] (vCP2242) ..... ≥ 5.3 log10 $FAID_{50}$
Influenza A/eq/Richmond/1/07 [H_3N_8] (vCP3011) ..... ≥ 5.3 log10 $FAID_{50}$
Clostridium tetani toxoid .....≥ 30 IU

3. PACKAGE SIZE

10 x 1 ml (10 doses).

4. TARGET SPECIES

Horses

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {dd/mm/yyyy}
Once opened use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

14. MARKETING AUTHORISATION NUMBERS

EU/2/03/038/005

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ProteqFlu-Te 

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

1 dose

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {dd/mm/yyyy}
Once opened use immediately.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

ProteqFlu-Te suspension for injection

2. Composition

One dose of 1 ml contains:

Active substances:
Influenza A/eq/Ohio/03 [H_3N_8] recombinant canarypox virus (vCP2242) ..... ≥ 5.3 log10 $FAID_{50}$*
Influenza A/eq/Richmond/1/07 [H_3N_8] recombinant canarypox virus (vCP3011) . ≥ 5.3 log10 $FAID_{50}$*
Clostridium tetani toxoid ..... ≥ 30 IU**

* vCP content checked by global $FAID_{50}$ (fluorescent assay infectious dose 50 %) and qPCR ratio between vCP.
** antitoxic antibody titre induced after repeated vaccination in guinea pig sera according to Ph. Eur.

Adjuvant:
Carbomer ..... 4 mg

Homogeneous opalescent suspension

3. Target species

Horses

4. Indications for use

Active immunisation of horses of 4 months of age or older against equine influenza to reduce clinical signs and virus excretion after infection, and against tetanus to prevent mortality.
Onset of immunity: 2 weeks after primary vaccination course.
Duration of immunity induced by the vaccination scheme:
- 5 months after the primary vaccination course;
- after the primary vaccination course and the booster injection 5 months later: 1 year with regard to equine influenza and 2 years with regard to tetanus.

5. Contraindications

None.

6. Special warnings

Vaccinate healthy animals only.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation:
Can be used during pregnancy and lactation.

Interactions with other medicinal products and other forms of interaction:
No interaction has been observed when the vaccine was administered simultaneously, but at a separate site, with Boehringer Ingelheim's inactivated vaccine against rabies.

Overdose:
Following the administration of overdoses of vaccine, no adverse events other than those described under section "Adverse events" have been observed.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. Adverse events

Horses:

Rare (1 to 10 animals / 10,000 animals treated):
Injection site swelling[1], increased skin temperature, muscle stiffness, injection site pain Elevated temperature[2]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Injection site abscess Apathy, decreased appetite[3] Hypersensitivity reaction[4]

[1]transient, usually regresses within 4 days; in rare occasions swelling can reach a diameter up to 15-20 cm, with duration up to 2–3 weeks that may require symptomatic treatment.
[2]max. 1.5 °C, for 1 day, exceptionally 2 days.
[3]the day after vaccination.
[4]which may require appropriate symptomatic treatment.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

8. Dosage for each species, routes and method of administration

Administer one dose (1 ml), by intramuscular injection, preferably in the neck region, according to the following schedule:
- Primary vaccination course with ProteqFlu-Te: first injection from 5–6 months of age, second injection 4–6 weeks later.
- Revaccination:
  - 5 months after primary vaccination course with ProteqFlu-Te.
  - Followed by:
    - against tetanus: injection of 1 dose at an interval of maximum 2 years with ProteqFlu-Te.
    - against equine influenza: injection of 1 dose every year, alternatively with ProteqFlu or ProteqFlu-Te, respecting an interval of maximum 2 years for the tetanus component.

In case of increased infection risk or insufficient colostrum intake, an additional initial injection of ProteqFlu-Te can be given at the age of 4 months followed by the full vaccination programme (primary vaccination course at 5–6 months of age and 4–6 weeks later followed by revaccination).

9. Advice on correct administration

For the administration of the vaccine, use sterile and antiseptic-free and/or disinfectant-free material.
Shake the vaccine gently before use.
Intramuscular use (preferably in the neck region).

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.

Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and vial label after Exp.

Shelf life after first opening the immediate packaging: use immediately.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/03/038/005

Box of 10 vials of 1 dose.

15. Date on which the package leaflet was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database.

16. Contact details

Marketing authorisation holder:
Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
Germany

Manufacturer responsible for batch release:
Boehringer Ingelheim Animal Health France SCS
Laboratoire Porte des Alpes
Rue de l'Aviation
69800 Saint-Priest
France

Local representatives and contact details to report suspected adverse reactions:

België/Belgique/Belgien
Boehringer Ingelheim Animal Health Belgium SA
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Danmark
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Deutschland
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Sverige
Boehringer Ingelheim Animal Health Nordics A/S
Tlf: +46 (0)40-23 34 00

United Kingdom (Northern Ireland)
Boehringer Ingelheim Animal Health UK Limited
Tel: + 44 1344 746957

17. Other information

The vaccine stimulates active immunity against equine influenza and tetanus.

The vaccine strains vCP2242 and vCP3011 are recombinant canarypox viruses expressing the haemagglutinin *HA* gene from the equine influenza virus strains A/eq/Ohio/03 (American strain, Florida sublineage clade 1) and A/eq/Richmond/1/07 (American strain, Florida sublineage clade 2), respectively. After inoculation, the viruses do not multiply in the horse but express the protective proteins. As a consequence, these components induce immunity against equine influenza virus (H_3N_8).