# ANNEX I

# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ProteqFlu-Te suspension for injection for horses

## 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.

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Suspension for injection.

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Horses

### 4.2 Indications for use, specifying the 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: 14 days 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.

### 4.3 Contraindications

None.

### 4.4 Special warnings

None.

### 4.5 Special precautions for use

**Special precautions for use in animals**
Only healthy animals should be vaccinated.

**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.

## 4.6 Adverse reactions (frequency and seriousness)

- A transient swelling which usually regresses within 4 days may appear at the injection site. 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.
- Pain, local hyperthermia and muscle stiffness can occur in rare cases.
- In very rare occasions, abscessation may be observed.
- A slight increase in temperature (max. 1.5 °C) may occur for 1 day, exceptionally 2 days.
- In exceptional circumstances, apathy and reduced appetite may be observed the day after vaccination.
- In exceptional circumstances a hypersensitivity reaction may occur, which may require appropriate symptomatic treatment.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

## 4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation.

## 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 at different sites and not mixed with Boehringer Ingelheim's inactivated vaccine against rabies.

## 4.9 Amounts to be administered and administration route

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).

### 4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Following the administration of overdoses of vaccine, no side-effects other than those described under section 4.6 have been observed.

### 4.11 Withdrawal period(s)

Zero days.

## 5. IMMUNOLOGICAL PROPERTIES

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 ($H_3N_8$).

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Carbomer
Sodium chloride
Disodium hydrogen orthophosphate
Monopotassium phosphate anhydrous
Water for injections

### 6.2 Major 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: 18 months.
Use immediately after opening.

### 6.4 Special precautions for storage

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

### 6.5 Nature and composition of immediate packaging

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

Box of 10 vials of 1 dose.

### 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 product should be disposed of in accordance with local requirements.

## 7. MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

## 8. MARKETING AUTHORISATION NUMBER(S)

EU/2/03/038/005

## 9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 6/03/2003
Date of last renewal: 6/03/2013

## 10. DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu).

## PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable