Issued: April 2023
AN: 00912/2022

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:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Homogeneous opalescent suspension
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: 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.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals:
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.

4.6 Adverse reactions (frequency and seriousness)

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.

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 not mixed with Boehringer Ingelheim's inactivated vaccine against rabies.

The vaccines should be given at different sites.

4.9 Amount(s) 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 adverse 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

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

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. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
Germany

8. MARKETING AUTHORISATION NUMBER

Vm 04491/5048

9. DATE OF FIRST AUTHORISATION

06 March 2003

10. DATE OF REVISION OF THE TEXT

April 2023

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Approved 28 April 2023