Greveling Holding BV

PROTEQ FLU TE

Composition

One dose of 1ml contains:

Influenza A/eq/Ohio/0s [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.

Characteristics

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].

Indications

Active immunisation of horses of 4 months of age or older against equine influenza to reduce clinical sings 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.

Dosage and administration

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 1 dose (1ml), by intramuscular injection, preferably in the neck region, according to the following schedule:

- Primary vaccination course with ProteqFlu-Te: first injection from 5-6months of age, second injection 4-6 weeks later.
- Revaccination:
    - 5 months after primary vaccination course with ProteqFlu-Fe.
    - 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 revaccinations.

Adverse reactions

- 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 15-20cm, with duration up to 203 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 eh day after vaccination.
- In exceptional circumstances a hypersensitivity reaction may occur, which may require appropriate symptomatic treatment.

Precautions

Only healthy animals should be vaccinated.
Can be used during pregnancy and lactation.
Special precautions taken by the person administering the product;
In case of accidental self-injection, seek medical advice immediately and show package leaflet or label to the physician.

Storage

Store at room temperature +2 - +8°C. Keep out of sight and reach of children

Presentation

Box of 10 vials of 1 dose

Registration (international)

EU/2/03/038/005