ProteqFlu-Te

FOR ANIMAL USE ONLY
South Africa Reg. No. G3436 Act 36/1947
Namibia Reg. No. V07/24.6/533 (NS0)

ProteqFlu TE is an adjuvanted vaccine against equine influenza (recombinant canarypox-equine influenza viruses vCP2242 and vCP3011) and tetanus toxoid.

INDICATIONS

For the active immunisation of horses of 4 months of age and older against equine influenza to reduce clinical signs and virus excretion after vaccination and against tetanus to prevent mortality. ProteqFlu TE can be used during pregnancy and lactation.

COMPOSITION

One dose (1 ml) contains

Active ingredients:

Influenza A/equi-2/**Ohio/03** recombinant Canarypox virus (vCP2242)
≥ 5.3 log10 FAID50*
Influenza A/equi-2/**Richmond/1/07** recombinant Canarypox virus (vCP3011)
≥ 5.3 log10 FAID50*
** vCP content checked by global FAID50 (Fluorescent Assay Infectious Dose 50%) and qPCR ratio between vCP*
Clostridium tetani toxoid.

Adjuvant:

Carbomer.

Excipient:

Gentamycin (traces).
Formaldehyde (traces).

DOSAGE AND DIRECTIONS FOR USE

- Use only as directed.
- In the case of an overdose, no side effects other than those stated below have been observed.
- 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 (1ml), by intramuscular injection, preferably in the neck region, according to the following programme:

- **Primary vaccination:** first injection from 5–6 months of age, second injection 4-6 weeks later.
- **Revaccination:**
  - o 5 months after primary vaccination with PROTEQFLU-TE.
  - o 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 vaccination of PROTEQFLU-TE can be given at 4 months of age followed by the full vaccination programme (primary vaccination at 5-6 months of age and 4-6 weeks later followed by revaccination).

Onset of immunity: 14 days after primary vaccination.
Duration of immunity:

- 5 months after primary vaccination;
- After primary vaccination and the revaccination 5 months later: 1 year with regard to equine influenza and 2 years with regard to tetanus.

ProteQ Flu-Te

PRESENTATION

PROTEQFLU-TE is presented in a container of 10 x 1 mℓ vials of suspension for injection.

STORAGE

- Store between +2 ºC and +8 ºC in a refrigerator.
- Do not freeze.
- Protect from light.

WARNINGS

- Keep out of reach of children, uninformed persons and animals.
- Only vaccinate healthy equidae.
- Do not mix with any other veterinary medicinal product.
- In case of accidental self-injection seek medical advice immediately and show him/her the package insert.

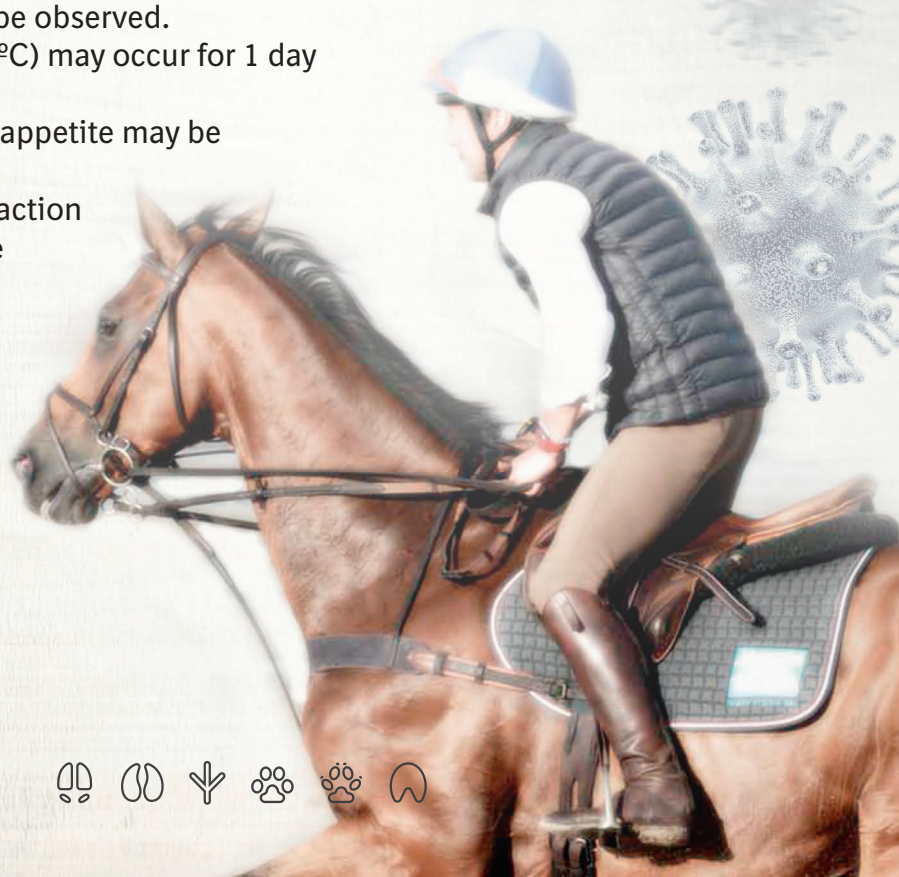
Immunological properties

The vaccine stimulates active immunity against equine influenza and tetanus. The vaccine strains vCP2242 and vCP3011 are recombinant canarypox viruses expressing the haemaglutinin (HA) genes of equine influenza virus strain A/equi-2/Ohio/03 (Florida sub-lineage) and A/equi-2/Richmond/1/07 (Florida sub-lineage), respectively. After inoculation, the viruses do not multiply in the horse but express the protective proteins. As a consequence, these components induce an immune status against equine influenza virus (H3N8).

SIDE EFFECTS

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 ºC) may occur for 1 day (max 2 days).
- In exceptional cases, apathy and reduced appetite may be observed the day after vaccination.
- In exceptional cases, a hypersensitivity reaction may occur, which may require appropriate supportive treatment.



REGISTRATION HOLDER

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