

# ProteqFlu

## FOR ANIMAL USE ONLY

South Africa Reg. No. G3435 Act 36/1947

Namibia Reg. No. V07/24.6/532 (NS0)



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

## 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. ProteqFlu 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 log<sub>10</sub> FAID50\*

Influenza A/equi-2/**Richmond/1/07** recombinant Canarypox virus (vCP3011)

≥ 5.3 log<sub>10</sub> FAID50\*

\* vCP content checked by global FAID50 (Fluorescent Assay Infectious Dose 50%) and qPCR ratio between vCP

### Adjuvant:

Carbomer.

### Excipient:

Gentamycin (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.

### 1<sup>st</sup> programme - vaccination against equine influenza:

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:** 5 months after primary vaccination.
- **Booster vaccination:** Annually.

In case of increased infection risk or insufficient colostrum intake, an initial vaccination 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).

### 2<sup>nd</sup> programme - vaccination against equine influenza and tetanus:

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

- **Primary vaccination with PROTEQFLU-TE:** first injection from 5-6 months of age, second injection 4-6 weeks later.
- **Revaccination:** 5 months after primary vaccination followed by annual booster injections 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 initial vaccination 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 vaccinations and 1 year after primary vaccinations and the revaccination 5 months later.

## PRESENTATION

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

## STORAGE

- Store between +2 °C and +8 °C 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. The vaccine strains vCP2242 and vCP3011 are recombinant canarypox viruses expressing the haemagglutinin (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 °C) 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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