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EPAR summary for the public

ProteqFlu-Te

Equine influenza and tetanus vaccine

This document is a summary of the European Public Assessment Report. Its purpose is to explain how the assessment done by the Committee for Medicinal Products for Veterinary Use (CVMP) on the basis of the documentation provided, led to the recommendations on the conditions of use.

This document cannot replace a face-to-face discussion with your veterinarian. If you need more information about your animal's medical condition or treatment, contact your veterinarian. If you want more information on the basis of the CVMP recommendations, read the scientific discussion (also part of the EPAR).

What is ProteqFlu-Te?

ProteqFlu-Te is a vaccine for use in horses. It contains parts of two equine influenza (flu) strains, which have been inserted into two canarypox vector (carrier) viruses respectively, and a tetanus toxoid (chemically weakened toxins from the tetanus bacterium). ProteqFlu-Te is available as a suspension for injection.

What is ProteqFlu-Te used for?

ProteqFlu-Te is used to vaccinate horses from 4 months of age against equine influenza and tetanus. The vaccine reduces the clinical signs of equine influenza and the excretion (shedding) of the virus after infection. Equine influenza is a highly contagious disease that is very common in horses but rarely causes death. The vaccine also stimulates protection against tetanus to prevent mortality. Tetanus is an acute, often fatal disease caused by the neurotoxin of the bacterium *Clostridium tetani*. The disease, which usually originates from contaminated wounds, is characterised by overall rigidity (stiffness) and convulsive spasms of the muscles. The muscle stiffness usually starts from the jaw and neck, then affects the whole body. Horses are among the most susceptible species to tetanus.

The vaccine is given as an intramuscular injection (injection into a muscle). Horses should receive a primary vaccination, consisting of two injections at 5–6 months of age, given 4–6 weeks apart.

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This should be followed by revaccination 5 months later, and afterwards by booster vaccinations every two years for protection against tetanus or for protection against influenza vaccination every year alternating with ProteqFlu or ProteqFlu-Te, respecting an interval of maximum two years for tetanus. In case of increased risk of infection or insufficient intake of colostrum (first milk), an additional initial injection can be given at the age of 4 months, followed by the full vaccination programme (primary vaccination and following revaccinations).

How does ProteqFlu-Te work?

ProteqFlu-Te is a vaccine which was produced with the use of recombinant DNA technology. This means that a gene from two different equine influenza strains (A/eq/Ohio/03 and A/eq/Richmond/1/07) was inserted in to the canarypox vector viruses, which do not produce disease in horses, allowing the vector to produce specific proteins from these influenza strains. The vaccine also contains a tetanus toxoid which is a tetanus toxin processed in order to decrease its toxic effect, but retain its antigenic power.

Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against diseases. When ProteqFlu-Te is given to horses, the animals' immune system recognises the specific proteins from the equine influenza strains and the tetanus toxoid as 'foreign' and makes antibodies against them. The immune system will then be able to make those protective antibodies more quickly when the animal is naturally exposed to the equine flu viruses and the tetanus bacterium. This will help to protect against equine influenza and tetanus.

ProteqFlu-Te contains an adjuvant (carbomer) to enhance the immune response.

How has ProteqFlu-Te been studied?

The effectiveness of ProteqFlu-Te was first assessed in several laboratory and field studies. In laboratory studies, horses were challenged (infected) with equine influenza virus and the clinical signs and the excretion of the influenza virus after the challenge were compared between vaccinated and control animals (non-vaccinated animals or those vaccinated with a competitive product). The measure of effectiveness in all studies was antibody levels of against the two influenza vaccine strains and against tetanus toxoid.

The immunogenicity of the current formulation of the vaccine was confirmed in 15 foals.

What benefit has ProteqFlu-Te shown during the studies?

The studies showed that ProteqFlu-Te was effective in reducing clinical signs and virus excretion after infection with equine influenza, and against tetanus to prevent mortality from 14 days after primary vaccination. The duration of protection was 5 months after primary vaccination and one year for the equine influenza and two years for the tetanus after the third vaccination.

The current formulation of ProteqFlu-Te produced similar antibody responses against the two flu strains and tetanus toxoid included in the vaccine to those seen in the main studies.

What is the risk associated with ProteqFlu-Te?

A short lived swelling at the injection site may occur (max. diameter 5 cm) which decreases within 4 days.

What are the precautions for the person who gives the medicine or comes into contact with the animal?

In case of accidental self-injection, medical advice should be sought immediately and the package leaflet or the label shown to the doctor.

What is the withdrawal period?

The withdrawal period is the time allowed after administration of the medicine and before the animal can be slaughtered and the meat used for consumption or milk used for consumption. The withdrawal period for ProtequFlu-Te for meat and milk is zero days.

Why has ProteqFlu-Te been approved?

The Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of ProteqFlu-Te exceed the risks for the approved indication and recommended that ProteqFlu-Te be given a marketing authorisation. The benefit-risk balance may be found in the scientific discussion module of this EPAR.

Other information about ProteqFlu-Te:

The European Commission granted a marketing authorisation valid throughout the European Union, for ProteqFlu-Te on 6 March 2003. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated in June 2014.