



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/414643/2008  
EMA/V/C/095

## EPAR summary for the public

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# Equilis Prequenza 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 Equilis Prequenza Te?

Equilis Prequenza Te is a vaccine for use in horses. It contains inactivated (killed) whole virus of two equine influenza (flu) strains ('A/equine-2/South Africa/4/03' and 'A/equine-2/Newmarket/2/93') and tetanus toxoid (chemically inactivated toxin from the tetanus bacterium). The vaccine is available as a suspension for injection.

### What is Equilis Prequenza Te used for?

Equilis Prequenza Te is used to vaccinate horses from six months of age against equine influenza and tetanus. The vaccine reduces the 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 that rarely causes death.

The vaccine also stimulates protection against tetanus to prevent mortality. Tetanus is an acute, often fatal disease caused by the toxin (poison) produced by the bacterium *Clostridium tetani*. The disease, which usually originates from contaminated wounds, is characterised by overall rigidity (stiffness) and convulsive spasms of the muscles. Horses are very susceptible to tetanus.

The vaccine is given as an injection into a muscle. Horses should receive a primary vaccination, consisting of two injections given four weeks apart. To retain protection, horses need to be revaccinated. For the full vaccination schedule see the package leaflet.

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## **How does Equilis Prequenza Te work?**

Equilis Prequenza Te contains inactivated whole virus of the influenza strains against which the vaccine is indicated. These equine influenza viruses have been inactivated so that they can no longer cause disease. The vaccine also contains purified tetanus toxoid. The toxoid is a toxin processed in order to remove its toxic effect, but still allow it to be recognised by the immune system.

Vaccines work by 'teaching' the immune system how to defend itself against diseases. When a horse is given the vaccine, the immune system recognises the virus and toxoid as 'foreign' and makes antibodies against them. In the future, the immune system will be able to produce antibodies more quickly when it is exposed to these virus strains or to the unmodified toxin. The antibodies will then help to protect against equine influenza and tetanus.

The viruses included in the current formulation of Equilis Prequenza Te are grown in mammalian cells, unlike those in the initial formulation, which were grown in hens' eggs.

The vaccine also contains an 'adjuvant' to enhance the immune response.

## **How has Equilis Prequenza Te been studied?**

The safety of the initial formulation of Equilis Prequenza Te was studied in several studies under laboratory and field conditions in a large number of horses, from 2 months of age.

The effectiveness of Equilis Prequenza Te was initially studied in several trials under laboratory and field conditions. For ethical reasons no challenge (infection) experiment was performed against tetanus. The main measure of effectiveness of Equilis Prequenza Te against equine influenza was the production of protective levels of antibodies against the influenza components. The studies also compared the clinical signs and virus excretion of a group of vaccinated animals with those of a control group, (i.e. which did not receive the vaccine or received a competitive product). Regarding tetanus, the main measure of effectiveness was the production of protective levels of antibodies against tetanus toxoid.

The effectiveness of the current formulation of the vaccine has been assessed in additional laboratory studies.

## **What benefit has Equilis Prequenza Te shown during the studies?**

The studies showed that Equilis Prequenza Te is an effective vaccine against equine influenza to reduce clinical signs and virus excretion after infection, and against tetanus to prevent mortality, in horses from 6 months of age. Horses developed protective levels of antibodies two weeks after primary vaccination. The duration of protection was five months after primary vaccination and 12 months after the first revaccination for equine influenza and 17 months after primary vaccination and 24 months after the first revaccination for tetanus.

The current formulation of Equine Prequenza Te has been shown to produce similar results to those shown in the initial studies.

## **What is the risk associated with Equilis Prequenza Te?**

A hard or soft swelling may occur at the injection site. The swelling is expected to decrease within two days. Pain at the injection site can occur rarely. In very rare cases fever may occur for one day, and up to three days in exceptional circumstances.

## **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 time to allow before the animal can be slaughtered and the meat used for human consumption (withdrawal period)?**

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

## **Why has Equilis Prequenza Te been approved?**

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

## **Other information about Equilis Prequenza Te:**

The European Commission granted a marketing authorisation valid throughout the European Union, for Equilis Prequenza Te on 8 July 2005. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated in February 2013.