EMA/414991/2008
EMEA/V/C/094

EPAR summary for the public

Equilis Prequenza

Equine influenza 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?

Equilis Prequenza 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'). The vaccine is available as a suspension for injection.

What is Equilis Prequenza used for?

Equilis Prequenza is used to vaccinate horses from six months of age against equine influenza. Equine influenza is a highly contagious disease that is very common in horses but that rarely causes death. The vaccine reduces the signs of equine influenza and the excretion (shedding) of the virus after infection.

The vaccine is given as an injection into a muscle. Horses should receive a primary vaccination, consisting of two injections given four weeks apart. This should be followed by a third vaccination five months later, and afterwards by yearly revaccinations.

How does Equilis Prequenza work?

Equilis Prequenza 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.

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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 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 any of these virus strains. The antibodies will then help to protect against the disease caused by these strains of the equine influenza virus. The viruses included in the current formulation of Equilis Prequenza 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 been studied?

The safety of the initial formulation of Equilis Prequenza 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 was initially studied in several trials under laboratory and field conditions. Most of the studies used Equilis Prequenza Te, a vaccine which protects against tetanus as well as the strains of equine influenza included in Equilis Prequenza. The main measure of effectiveness 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.

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

What benefit has Equilis Prequenza shown during the studies?

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

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

What is the risk associated with Equilis Prequenza?

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 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 for meat and milk is zero days.

Why has Equilis Prequenza been approved?

The Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of Equilis Prequenza exceed the risks for the approved indications and recommended that Equilis Prequenza 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:

The European Commission granted a marketing authorisation valid throughout the European Union, for Equilis Prequenza 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.