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Equilis Te (*tetanus toxoid*)

An overview of Equilis Te and why it is authorised in the EU

What is Equilis Te and what is it used for?

Equilis Te is a veterinary vaccine used to protect horses from six months of age against tetanus to prevent mortality. Tetanus is an acute, often fatal disease caused by a neurotoxin 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 belong to the most susceptible species to tetanus. It contains the active substance tetanus toxoid.

How is Equilis Te used?

The medicine can only be obtained with a prescription.

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 against tetanus, horses need to be revaccinated. The first revaccination should be no later than 17 months after primary vaccination. Afterwards, a maximum interval of two years is recommended.

For more information about using Equilis Te, see the package leaflet or contact your veterinarian or pharmacist.

How does Equilis Te work?

Equilis Te is a vaccine containing purified tetanus toxoid. The toxoid is a toxin processed in order to remove its toxic effect, but retain its antigenic properties.

Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against diseases. When the product is given to horses, it helps the animals' immune system to react quicker when the animal is naturally exposed to the Clostridium tetani bacterium. This helps to protect against tetanus. The vaccine also contains an 'adjuvant' to stimulate a better immune response.

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What benefits of Equilis Te have been shown in studies?

The safety of Equilis Te was investigated in several studies under laboratory and field conditions in a large number of horses, from 2 months of age. All studies were performed with Equilis Prequenza Te (see below). It was concluded that the product is well tolerated by horses of different age. Studies in pregnant mares were also performed. No negative influence on gestation, foaling and offspring of mares was observed after vaccination at different times during pregnancy.

The effectiveness of Equilis Te has been studied in several trials under laboratory and field conditions. Most of the studies were performed with Equilis Prequenza Te, a vaccine that protects against equine influenza as well as against tetanus. For ethical reasons, no challenge (infection) experiment was performed against tetanus. The main measure of effectiveness was the production of protective levels of antibodies against tetanus toxoid after vaccination.

The studies showed that Equilis Te is an effective vaccine against tetanus to prevent mortality in horses from 6 months of age. Horses developed protection two weeks after primary vaccination. The duration of protection against tetanus was 17 months after primary vaccination and 24 months after the first revaccination.

What are the risks associated with Equilis Te?

Swelling (max. diameter 5 cm) may occur at the injection site, either as diffuse hard or soft swelling. The swelling is expected to decrease within two days. Pain at the injection site can occur occasionally. In some cases fever may occur for one day, and up to three days in exceptional circumstances.

For the full list of side effects and restrictions of Equilis Te, see the package leaflet.

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

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the doctor.

What is the withdrawal period in food-producing animals?

The withdrawal period is the time required after administration of a medicine before an animal can be slaughtered and the meat used for human consumption. The withdrawal period of the product is zero days.

Why is Equilis Te authorised in the EU?

The European Medicines Agency decided that Equilis Te's benefits are greater than its risks and it can be authorised for use in the EU.

Other information about Equilis Te

Equilis Te received a marketing authorisation valid throughout the EU on 8 July 2005.

Further information on Equilis Te can be found on the Agency's website: ema.europa.eu/en/medicines/veterinary/EPAR/equilis-te

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