



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## Equilis StrepE (*live deletion mutant Streptococcus equi strain TW928*)

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

### What is Equilis StrepE and what is it used for?

Equilis StrepE is a veterinary vaccine used to protect horses against the respiratory disease caused by the bacteria *Streptococcus equi*. The highly contagious and common disease caused by this bacterium is commonly called 'strangles'. In strangles, the lymph nodes in the head can become large enough to block the airway, causing the horse to have difficulty breathing. This is a highly contagious disease and a common bacterial infection in horses. Equilis StrepE reduces the clinical signs of disease and the occurrence of lymph node abscesses (collections of pus).

Equilis StrepE contains the active substance live deletion mutant *Streptococcus equi* strain TW928.

### How is Equilis StrepE used?

Equilis StrepE is available as a lyophilisate (freeze-dried pellet) which is made up into a suspension for injection. The vaccine can only be obtained with a prescription.

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

### How does Equilis StrepE work?

Equilis StrepE is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against diseases. Equilis StrepE contains small amounts of a type of bacterium called *S. equi*. When a horse is given the vaccine, the immune system recognises the bacteria as 'foreign' and makes antibodies against them. In the future, the immune system will be able to produce antibodies more quickly when it is again exposed to the bacteria. The bacterium strain included in Equilis StrepE has had some genes removed, so that it grows less well inside the horse's body and is less likely to cause disease. This makes it suitable for use in a vaccine.

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## **What benefits of Equilis StrepE have been shown in studies?**

The vaccine is given as a 0.2 ml injection into the inside of the upper lip. The effectiveness of Equilis StrepE has been studied in safety studies and one main field study. The horses had not had any disease including strangles in the past and had never been vaccinated. The results of the safety trials demonstrate that Equilis StrepE is safe for horses from four months of age onwards, as the local and systemic reactions observed after single, repeated dose and overdose treatment were considered acceptable. Horses from four months of age should receive a second injection after four weeks. All horses should be revaccinated every three months to maintain immunity. Equilis StrepE is only for use in healthy horses that are at risk of *S. equi* infection due to contact with horses from areas where the bacterium is known to be present.

The studies demonstrated that Equilis StrepE is effective in the active immunisation of horses from 4 months of age against *Streptococcus equi* to reduce clinical signs and occurrence of lymph node abscesses. Fewer of the horses receiving Equilis StrepE had symptoms of strangles. They also had fewer abscesses and fewer lymph nodes affected.

## **What are the risks associated with Equilis StrepE?**

Only healthy horses which are at risk of infection should be vaccinated. After injection, swelling will develop at the injection site within four hours and the injection site may become warm or painful. The reaction is greatest at two to three days after injection, but the area affected should not be larger than 3 by 8 cm. The swelling should disappear within three weeks and should have no effect on the horse's appetite, nor cause it any discomfort. In very rare cases an abscess and discharge may develop at the injection site, and the lymph nodes in the head may enlarge, which may be painful for a short while.

An increase in body temperature of up to 2°C may occur on the day of vaccination. In rare cases, loss of appetite, fever and shivering may be observed. In very rare cases depression may develop.

For the full list of side effects and restrictions of Equilis StrepE, 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, which can cause inflammation with severe pain and swelling, seek medical advice immediately and show the package leaflet or the label to the doctor, even if only a small amount has been injected.

## **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 for meat from horses treated with Equilis StrepE is zero days.

## **Why is Equilis StrepE authorised in the EU?**

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

## **Other information about Equilis StrepE**

Equilis StrepE received a marketing authorisation valid throughout the EU on 7 May 2004.

Further information on Equilis StrepE can be found on the Agency's website:  
[ema.europa.eu/medicines/veterinary/EPAR/equilis-strepe](http://ema.europa.eu/medicines/veterinary/EPAR/equilis-strepe).

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