EMA/243127/2013
EMEA/V/C/002241

EPAR summary for the public

Equilis West Nile

Flavivirus strain YF-WN

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 West Nile?

Equilis West Nile is a veterinary vaccine that contains inactivated (killed) West Nile virus. It contains a strain called Yellow Fever-West Nile (YF-WN). It is available as a suspension for injection.

What is Equilis West Nile used for?

Equilis West Nile is used to vaccinate horses from six months of age against West Nile virus. West Nile virus is an infection that is transmitted by mosquitoes and can cause severe disease and fatal brain infections in infected horses.

The vaccine is initially given to horses over six months of age as two injections into the muscle, three to five weeks apart. After this a single injection should be given each year as a booster.

How does Equilis West Nile work?

Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. Equilis West Nile contains small amounts of West Nile virus that has been inactivated (killed) so that it can no longer cause disease. When Equilis West Nile is given to horses, their immune system recognises the virus contained in the vaccine as 'foreign' and makes antibodies to defend against it. In future if the animals are exposed to West Nile virus the immune system will be able to respond more quickly. This will help to protect against the disease.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

Equilis West Nile contains an adjuvant to enhance the immune response.

How has Equilis West Nile been studied?

The effectiveness of Equilis West Nile was first studied in a number of laboratory studies that examined how long it took to achieve protection after vaccination, and how long the protection lasted.

Equilis West Nile was also studied in three field studies. The first of these involved 173 horses at least six months of age, in which vaccination with Equilis West Nile was compared with a placebo (dummy injection). The vaccine was also compared with placebo in two other field studies involving pregnant mares. The first involved 128 pregnant mares of mixed breeds and the second involved 41 pregnant thoroughbred mares. The measure of effectiveness in all the field studies was the number of horses which developed protective antibody levels against West Nile virus.

What benefit has Equilis West Nile shown during the studies?

The laboratory studies showed that horses developed protection two weeks after primary vaccination. The duration of protection was 12 months after primary vaccination as well as after the yearly single booster vaccination.

The main field study showed that vaccination with Equilis West Nile when given as recommended produced protective antibody levels in 94% of the vaccinated horses at day 42 of the study. The studies in pregnant mares showed that 89% of the vaccinated mixed-breed mares and 95% of the vaccinated thoroughbred mares produced protective antibody levels.

What is the risk associated with Equilis West Nile?

A mild short-lived swelling may develop at the injection site which resolves in one to five days. A slight increase in body temperature, by up to 1.5 °C, may occur for one or two days.

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

If the product is accidentally self-injected, medical advice should be sought immediately and the package leaflet or 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 human consumption or milk used for human consumption. The withdrawal period for Equilis West Nile is zero days.

Why has Equilis West Nile been approved?

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

Other information about Equilis West Nile:

The European Commission granted a marketing authorisation valid throughout the European Union, for Equilis West Nile on 6 June 2013. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated in April 2013.