



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/510730/2008  
EMA/V/C/000137

## EPAR summary for the public

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# Equip WNV

## West Nile virus strain VM-2

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 Equip WNV?

Equip WNV is a vaccine that contains inactivated (killed) West Nile virus. It is available as an emulsion for injection.

### What is Equip WNV used for?

Equip WNV 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. Outbreaks of West Nile virus in Europe have been caused by two strains of the virus called lineage 1 and lineage 2. The vaccine is used to reduce the number of horses with the West Nile virus lineage 1 or 2 in their blood (viraemia) and to reduce the severity and duration of clinical signs of West Nile virus disease caused by lineage 2 strains.

The vaccine is initially given as two injections into the muscles in the neck. The first is given from six month of age and the second is given three to five weeks later. After this a single injection should be given each year as a booster.



## **How does Equip WNV work?**

Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. When Equip WNV is given to horses, their immune system recognises the virus contained in the vaccine as 'foreign' and makes antibodies to defend against it. In the 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.

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

## **How has Equip WNV been studied?**

The effectiveness of Equip WNV was studied in a number of laboratory studies that examined how long it took to achieve protection after vaccination and how long protection lasted in horses injected with West Nile virus lineage 1. In addition a laboratory study was performed in which vaccinated and non-vaccinated horses were injected with West Nile virus lineage 2 directly into the central nervous system three weeks after initial vaccination. The main measure of effectiveness was reduction of virus in the blood and the frequency and duration of clinical signs. A number of field trials were also conducted involving vaccinated and non-vaccinated horses.

## **What benefit has Equip WNV shown during the studies?**

The laboratory studies showed that horses developed protection three weeks after the primary vaccination course. The duration of protection was 12 months after the primary vaccination course for lineage 1 strains but was not established for lineage 2 strains.

The field studies showed that Equip WNV protects horses from West Nile virus by reducing the number of viraemic horses after infection with West Nile virus lineage 1 or 2 strains and by reducing the duration and severity of clinical signs against lineage 2 strains.

## **What is the risk associated with Equip WNV?**

A small number of animals may show temporary local reactions, in the form of a mild, local swelling at the injection site post vaccination (maximum 1 cm in diameter), that resolve by themselves within 1 to 2 days. It is sometimes associated with pain and very rarely with mild depression. In very rare cases a higher temperature may occur for up to 2 days. As with any vaccine rare, occasional allergic reactions may occur.

## **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, ingested or spilled onto skin 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 Equip WNV is zero days.

## **Why has Equip WNV been approved?**

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

## **Other information about Equip WNV:**

The European Commission granted a marketing authorisation valid throughout the European Union for Equip WNV on 21 November 2008. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated in September 2013.