12 April 2013
EMA/CVMP/161880/2013
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Equilis West Nile

International non-proprietary name (INN): Inactivated chimeric Flavivirus strain YF-WN

On 11 April 2013, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2] recommending the granting of a marketing authorisation for the veterinary medicinal product Equilis West Nile, suspension for injection, intended for the active immunisation of horses against West Nile virus (WNV) to reduce clinical signs of disease and lesions in the brain and to reduce viraemia. The applicant for this veterinary medicinal product is Intervet International B.V.

The active substance of Equilis West Nile is inactivated chimeric flavivirus strain YF-WN. The product is an inactivated viral vaccine, ATCvet code: QI05AA10, which stimulates active immunity against West Nile virus in horses.

The benefits of Equilis West Nile are the reduction of clinical signs of disease and lesions in the brain and the reduction of viraemia. The most common adverse reactions are a mild transient swelling at the injection site (max. 3 cm in diameter). This swelling normally resolves within 1 to 5 days. A mild body temperature increase (max. 1.5 °C) may also occur for 1 to 2 days.

Detailed conditions for the use of this product will be described in the summary of product characteristics (SPC) which will be published in the European public assessment report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Equilis West Nile and therefore recommends the granting of the marketing authorisation

[1] Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued within 90 days from adoption of the opinion.
[2] Applicants may appeal any CVMP opinion, provided they notify the European Medicines Agency in writing of their intention to appeal within 15 days of receipt of the opinion.

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