SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Proteq West Nile suspension for injection for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 1 ml contains:

Active substance:
West Nile recombinant canarypox virus (vCP2017).....6.0 to 7.8 log10 CCID*50
* Cell culture infectious dose 50 %

Adjuvant:
Carbomer……..4 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.
Homogeneous opalescent suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Horses

4.2 Indications for use, specifying the target species

Active immunisation of horses from 5 months of age against West Nile disease by reducing the number of viraemic horses. If clinical signs are present, their duration and severity are reduced.

Onset of immunity: 4 weeks after the first dose of the primary vaccination course. In order to achieve full protection, the full vaccination course of two doses must be given.
Duration of immunity: 1 year after a full primary vaccination course of two injections.

4.3 Contraindications

None.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Vaccinate only healthy animals.
The safety of the vaccine has been demonstrated in foals from 5 months of age. However, the vaccine has also been shown to be safe in a field study including animals of 2 months of age.

Vaccination may interfere with existing sero-epidemiological surveys. However, since the IgM response following vaccination is infrequent, a positive IgM-ELISA test result is a strong indicator of natural infection with West Nile Virus. If infection is suspected as a result of a positive IgM response, additional testing would need to be conducted to conclusively determine whether the animal was infected or vaccinated.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

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

4.6 Adverse reactions (frequency and seriousness)

A transient swelling (max. diameter 5 cm) which resolves within 4 days may appear commonly at the injection site.
Pain and local hyperthermia can occur in rare cases.
A slight increase in temperature (max. 1.5 °C) may occur in rare cases for 1 day, exceptionally 2 days. Apathy, usually resolving within two days, and reduced appetite may be observed in rare cases the day after vaccination.
A hypersensitivity reaction may occur in rare cases, which may require appropriate symptomatic treatment.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

4.9 Amounts to be administered and administration route

For intramuscular use.
Shake the vaccine gently before use.

Administer one dose of 1 ml, by intramuscular injection, preferably in the neck region, according to the following schedule:

- Primary vaccination course: first injection from 5 months of age, second injection 4-6 weeks later,
- Revaccination: a sufficient degree of protection should be achieved after an annual booster injection with a single dose although this schedule has not been fully validated.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No adverse reactions other than those already mentioned in section 4.6 have been observed after the administration of more than 10 doses.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for equidae, other immunologicals.
ATC vet code: QI05AX.

To stimulate active immunity against West Nile virus.

The vaccine strain vCP2017 is a recombinant canarypox virus expressing the preM/E genes of West Nile virus. After inoculation, the virus does not multiply in the horse but expresses the protective proteins. As a consequence, these proteins induce protective immunity against equine West Nile disease.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Disodium phosphate dihydrate
Potassium dihydrogen phosphate
Water for injections

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 27 months.
Use immediately after opening.

6.4 Special precautions for storage

Store and transport refrigerated (2 °C-8 °C)
Do not freeze
Protect from light

6.5 Nature and composition of immediate packaging

Type I glass vial, with a butyl elastomer closure, sealed with an aluminium cap.

Box of 1, 2, 5 or 10 vial(s) of 1 dose.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant approved for use by the competent authorities.

7. MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

8. MARKETING AUTHORISATION NUMBER

Vm 04491/5046

9. DATE OF FIRST AUTHORISATION

05 August 2011

10. DATE OF REVISION OF THE TEXT

March 2022

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu/.

11. PROHIBITION OF SALE, SUPPLY AND/OR USE

The manufacture, import, possession, sale, supply and/or use of Proteq West Nile may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation. Any person intending to manufacture, import, possess, sell, supply and use Proteq West Nile must consult the relevant Member State's competent authority on the current vaccination policies prior to the manufacture, import, possession, sale, supply and/or use.

Approved 11 March 2022