

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

Excipients:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Homogeneous opalescent suspension.

Suspension for injection.

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

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in 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.

Special precautions for the protection of the environment:

Not applicable.

4.6 Adverse reactions (frequency and seriousness)

Horses:

Common (1 to 10 animals / 100 animals treated):	Injection site swelling ¹
Rare (1 to 10 animals / 10,000 animals treated):	Injection site pain, increased skin temperature Elevated temperature ² Apathy ³ , decreased appetite ⁴ Hypersensitivity reaction ⁵
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site abscess

¹ max. diameter 5 cm, which resolves within 4 days.

² max. 1.5 °C, for 1 day, exceptionally 2 days.

³ usually resolving within two days.

⁴ the day after vaccination.

⁵ which may require appropriate symptomatic treatment.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting

system. See the package leaflet for respective contact details.

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 Amount(s) 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 to 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 events 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

ATCvet 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.
Shelf life after first opening the immediate packaging: use immediately.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

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

November 2023

PROHIBITION OF SALE, SUPPLY AND/OR USE

Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Approved 17 November 2023

A handwritten signature in black ink, appearing to read "Hunter.", is positioned below the approval date.