ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {OUTER CARTON}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Proteq West Nile suspension for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each dose of 1 ml contains:
West Nile recombinant canarypox virus (vCP2017) ..... 6.0 to 7.8 $\log_{10}$ $CCID_{50}$
Carbomer ..... 4 mg

3. PACKAGE SIZE

1 x 1 dose
2 x 1 dose
5 x 1 dose
10 x 1 dose

4. TARGET SPECIES

Horses

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period: zero days

8. EXPIRY DATE

Exp. {dd/mm/yyyy}
Once opened use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Keep the vial in the outer carton.
Store and transport refrigerated.

Do not freeze.
Protect from light.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
Germany

14. MARKETING AUTHORISATION NUMBER

Vm 04491/5046

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V (‘To be supplied only on veterinary prescription’)

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
{Vial label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Proteq West Nile

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {dd/mm/yyyy}
Once opened use immediately.

5. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 dose

6. ROUTE(S) OF ADMINISTRATION

7. WITHDRAWAL PERIOD

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Proteq West Nile suspension for injection for horses

2. COMPOSITION

Each dose of 1 ml contains:

Active substance:
West Nile recombinant canarypox virus (vCP2017)…….6.0 to 7.8 $\log_{10}$ CCID*$_{50}$
* Cell culture infectious dose 50%

Adjuvant:
Carbomer.....4 mg

Homogeneous opalescent suspension.

3. TARGET SPECIES

Horses.

4. INDICATIONS FOR USE

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.

5. CONTRAINDICATIONS

None.

6. SPECIAL WARNING(S)

Vaccinate healthy animals only.

Special precautions for safe use in the target species:

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.

Pregnancy and lactation:

This vaccine can be used during pregnancy and lactation.

Interactions 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.

Overdose:

No adverse events other than those already mentioned in the section “Adverse events” have been observed after the administration of more than 10 doses.

Special restrictions for use and special conditions for 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.

Major incompatibilities:

Do not mix with any other veterinary medicinal product.

7. ADVERSE EVENTS

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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system {https://www.gov.uk/report-veterinary-medicine-problem}.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For intramuscular 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.

9. ADVICE ON CORRECT ADMINISTRATION

Shake the vaccine gently before use.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store and transport refrigerated (2 °C-8 °C).
Do not freeze.
Protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp.
Shelf life after first opening the immediate packaging: use immediately.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

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

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBER AND PACK SIZES

Vm 04491/5046

Box of 1, 2, 5 or 10 vial(s) of 1 dose.
Not all pack sizes may be marketed.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

November 2023

Find more product information by searching for the Product Information Database ‘PID’ on www.gov.uk

16. CONTACT DETAILS

Marketing authorisation holder:

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
Germany

Manufacturer responsible for batch release:

Boehringer Ingelheim Animal Health France SCS
Laboratoire Porte des Alpes
Rue de l'Aviation
69800 Saint-Priest
France

Local representatives and contact details to report suspected adverse reactions:

United Kingdom (Northern Ireland)
Boehringer Ingelheim Vetmedica GmbH
D-55216 Ingelheim/Rhein, Germany
Tel: +353 1 291 3985

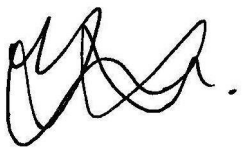
United Kingdom (Great Britain)
Boehringer Ingelheim Animal Health UK Limited
Bracknell, RG12 8YS, UK
Tel: + 44 1344 746957

17. OTHER INFORMATION

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.

For animal treatment only.



Approved: 18 April 2024