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 SUBSTANCES

Each dose of 1 ml contains:
Active substance:
West Nile (vCP2017) .....6.0 to 7.8 log10 $CCID_{50}$
Adjuvant:
Carbomer.....4 mg

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

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

5. TARGET SPECIES

Horses

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use

8. WITHDRAWAL PERIOD(S)

Withdrawal period: zero days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use

10. EXPIRY DATE

EXP {month/year}
Use immediately after opening

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated
Do not freeze
Protect from light

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE,

For animal treatment only. To be supplied only on veterinary prescription

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 04491/5046

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Proteq West Nile

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Read the package leaflet before use

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

1 dose

4. ROUTE(S) OF ADMINISTRATION

IM

5. WITHDRAWAL PERIOD(S)

Withdrawal: Zero days

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

B. PACKAGE LEAFLET

PACKAGE LEAFLET
Proteq West Nile suspension for injection for horses

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am 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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Proteq West Nile suspension for injection for horses

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENT

Homogeneous opalescent suspension for injection
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

4. INDICATIONS

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. CONTRAINDICATION

None.

6. ADVERSE REACTIONS

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).

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Horses.

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

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.

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.

Use immediately after opening.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP.

12. SPECIAL WARNINGS

Special precautions for use in animals:
Vaccinate only healthy animals.
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 warnings for each 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.

Pregnancy and lactation:
This vaccine can be used during pregnancy and lactation.

Overdose (symptoms, emergency procedures, antidotes):
No adverse reactions other than those already mentioned in the section “Adverse Reactions” have been observed after the administration of more than 10 doses.

Incompatibilities:
Do not mix with any other veterinary medicinal product.

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.

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.

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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

March 2022

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

15. 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.

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

Approved 11 March 2022