PARTICULARS TO APPEAR ON THE OUTER PACKAGE (Plastic box of 10 vials of suspension for injection, Plastic box of 50 vials of suspension for injection, Cardboard box of 2 vials of suspension for injection)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Purevax Rabies suspension for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each dose (1 ml) contains:
Rabies recombinant canarypox virus ..... (vCP65) ≥ $10^{6.8}$ $FAID_{50}$

3. PACKAGE SIZE

10 x 1 ml
50 x 1 ml
2 x 1 ml

4. TARGET SPECIES

Cats.

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {dd/mm/yyyy}
Once broached, use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Protect from light.
Do not freeze.

Keep the container in the outer carton.

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 NUMBERS

Vm 04491/5051

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

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS (vial)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Purevax Rabies

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {dd/mm/yyyy}

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

1 dose

6. ROUTE(S) OF ADMINISTRATION

SC

7. WITHDRAWAL PERIOD

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Purevax Rabies suspension for injection

2. COMPOSITION

Each dose of 1 ml contains:

Active substance:
Rabies recombinant canarypox virus (vCP65) ≥ $10^{6.8}$ FAID*$_{50}$
*Fluorescent assay infectious dose 50 %

Light pink to pale yellow homogeneous suspension

3. TARGET SPECIES

Cats.

4. INDICATIONS FOR USE

Active immunisation of cats 12 weeks of age and older to prevent mortality due to rabies infection.

Onset of immunity: 4 weeks after the primary vaccination course.
Duration of immunity after primary vaccination: 1 year.
Duration of immunity after revaccination: 3 years.

5. CONTRAINDICATIONS

None.

6. SPECIAL WARNING(S)

Vaccinate healthy animals only.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Canarypox recombinants are known to be safe for humans. Mild local and/or systemic adverse reactions related to the injection itself may be observed transitorily.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
Efficacy data are available which demonstrate that this vaccine can be administered at least 14 days before or after the administration of Boehringer Ingelheim non-adjuvanted vaccine against feline leukaemia.

Safety and efficacy data are available which demonstrate that this vaccine can be mixed and administered with Boehringer Ingelheim non-adjuvanted vaccines containing various combinations of feline viral rhinotracheitis, calicivirosis, panleukopenia and chlamydiosis components.

Overdose:
No adverse events other than those already mentioned in the section “Adverse Events” have been observed after the administration of 10 doses. The reactions may last longer.

Major incompatibilities:
Do not mix with any other veterinary medicinal product except those mentioned above.

7. ADVERSE EVENTS

Cats:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):
Apathy[1-2], mild anorexia[2], hyperthermia[2-3]
Injection site reactions (pain, swelling, warmth and erythema)[4]
Hypersensitivity reaction[5]

[1] Slight
[2] Usually lasting 1 or 2 days. Most of these reactions were noted during the 2 days following the vaccine injection.
[3] Above 39.5 °C
[4] Pain at palpation; limited swelling that may become nodular; usually disappearing within 1 or 2 weeks at most.
[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.

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

Subcutaneous use.

Administer one dose of 1 ml according to the following vaccination scheme:

Primary vaccination course: 1 injection from 12 weeks of age,
Revaccination: 1 year after primary vaccination, then at intervals of up to 3 years.

Travel to countries requiring a rabies serology test: experience has shown that some vaccinated animals, while protected, may not show the 0.5 IU/ml antibody titre required by some countries. Veterinary surgeons may wish to consider two vaccinations. The best time for a blood sample to be taken is around 28 days after vaccination.

9. ADVICE ON CORRECT ADMINISTRATION

Apply usual aseptic procedures.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store and transport refrigerated (2 °C – 8 °C).
Protect from light.
Do not freeze.
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

Medicines should not be disposed of via wastewater.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 04491/5051

Pack sizes:
Plastic box of 10 vials of 1 dose.
Plastic box of 50 vials of 1 dose.
Cardboard box of 2 vials of 1 dose.

Not all pack sizes may be marketed.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

October 2023

Find more product information by searching for the 'Product Information Database' or '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:

België/Belgique/Belgien
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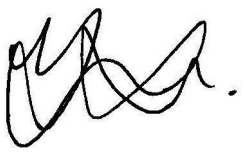
17. OTHER INFORMATION

Vaccines against rabies infection.

The vaccine strain vCP65 is a recombinant Canarypox virus expressing the glycoprotein G gene of rabies virus. After inoculation, the virus expresses the protective protein, but does not replicate in the cat. As a consequence, the vaccine stimulates active immunity against rabies virus in cats.

POM-V



Approved: 29 November 2023