SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Purevax Rabies suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of 1 ml contains:

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

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.
Light pink to pale yellow homogenous suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Cats.

4.2 Indications for use, specifying the target species

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.

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
Not applicable.

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.

4.6 Adverse reactions (frequency and seriousness)

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 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 also section “Contact details” of the package leaflet.

4.7 Use during pregnancy, lactation or lay

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

4.8 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.

4.9 Amount(s) to be administered and administration route

Subcutaneous use.

Apply usual aseptic procedures.

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

Primary vaccination: 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.

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 10 doses. The reactions may last longer.

4.11 Withdrawal period(s)

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for cats, live viral vaccine, rabies, recombinant live canarypox virus.

ATCvet Code: QI06AD08

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Potassium chloride
Sodium chloride
Potassium dihydrogen phosphate
Disodium phosphate dihydrate
Magnesium chloride hexahydrate
Calcium chloride dihydrate
Water for injections

6.2 Major Incompatibilities

Do not mix with any other veterinary medicinal product, except those mentioned in section 4.8 above.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 18 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 of 1 ml (1 dose) with a butyl elastomer closure, sealed with an aluminium cap.
Cardboard box of 2 x 1 ml.
Plastic box of 10 x 1 ml or 50 x 1 ml.

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 04491/5051

9. DATE OF FIRST AUTHORISATION

18 February 2011

10. DATE OF REVISION OF THE TEXT
PROHIBITION OF SALE, SUPPLY AND/OR USE

October 2023

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Approved 27 October 2023