SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

RABISIN

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml dose of vaccine contains:

Active substances:

Inactivated rabies virus, G52 strain	≥ 2.09 $\log_{10}$ OD_{50}* and ≥ 1 IU**

Adjuvant:

Aluminium (as hydroxide)	1.7 mg

Excipients:

Excipient	q.s.	1 ml

* when batch control is performed with an *in vitro* ELISA test
** when batch control is performed according to Ph. Eur. monograph 451

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs and cats.

4.2 Indications for use, specifying the target species

For active immunisation of dogs and cats, to reduce mortality and clinical signs due to rabies infection.
Immunity has been demonstrated 1 month after primary vaccination, and has been shown to persist up to the first booster dose, (1 year after primary vaccination) and up to 3 years following booster vaccination.

4.3 Contra-indications

None.

4.4 Special warnings for each target species

Do not vaccinate unhealthy animals.

4.5 Special precautions for use including special precautions to be taken by the person administering the medicinal product to animals

i) Special precautions for use in animals

Where a dog or a cat was vaccinated before 12 weeks of age, the primary vaccination scheme should be completed by an injection given at 12 weeks of age or older.

ii) Special precautions to be taken by the person administering the veterinary medicinal product to the animals

In the case of accidental self-injection, seek medical advice immediately and show the package leaflet or label to the physician.

4.6 Adverse reactions (frequency and seriousness)

Vaccination may sometimes induce a local reaction, as a small and transient swelling at the injection site (usually 2 – 3 cm diameter, persisting mostly up to 2 weeks, rarely up to 4 weeks).
Vaccination may exceptionally induce an anaphylactoid (hypersensitivity) reaction. In such a case, symptomatic treatment should be provided.

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy.

4.8 Interaction with other medicinal products and other forms of interaction

Safety and efficacy data are available which demonstrate that this vaccine can be administered the same day but not mixed with Boehringer Ingelheim's PUREVAX non-adjuvanted vaccines for cats.
In the case of products administered parenterally, the products should be given at different sites.
No information is available on the safety and efficacy of this vaccination when used with any other veterinary medicinal product except the products mentioned above. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be decided on a case by case basis.

4.9 Amounts to be administered and administration route

Inject one dose of 1 ml subcutaneously according to the following schedule:

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

UK Pet Travel Scheme (PETS): Animals intended for vaccination under the UK Pet Travel Scheme (PETS) must be identified by a permanently numbered

microchip. The microchip number must be recorded on the pet passport or official third country veterinary certificate at the time of rabies vaccination.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No other signs than those described under section 4.6 have been observed after the administration of an overdose of vaccine.

4.11 Withdrawal periods

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

Inactivated vaccine in adjuvant against rabies.
After administration, the vaccine stimulates active immunity against rabies.

ATCVet Code: QI07AA02

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

GMEM medium
Protein hydrolysates
Salts

6.2 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: 36 months.
Use immediately after opening.

6.4 Special precautions for storage

Store between +2°C and + 8°C, protected from light. Do not freeze.

6.5 Nature and composition of immediate packaging

Type I glass vials with butyl-elastomer closure.

Package sizes:
Bottle (glass) of 1 dose of suspension, box of 1 bottle
Bottle (glass) of 1 dose of suspension, box of 10 bottles
Bottle (glass) of 1 dose of suspension, box of 100 bottles

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, if appropriate

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products 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 61700/3092

9. DATE OF FIRST AUTHORISATION

28 October 2005

10. DATE OF REVISION OF THE TEXT

August 2025

Gavin Hall
Approved: 19 August 2025