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 substance(s):	
Inactivated rabies virus, G52 strain	≥ 2.09 $\log_{10} OD_{50}$*and ≥1 IU**
Adjuvant(s):	
Aluminium (as hydroxide)	1.7 mg
Excipient(s):	
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 a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Suspension for injection

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, dogs, horses, cats, mustelids and sheep

4.2 Indications for use, specifying the target species

For active immunisation of cattle, dogs, horses, cats, mustelids and sheep, 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).

In cats and dogs immunity has been shown to persist for up to 3 years following booster vaccination.

4.3 Contraindications

Do not inject the vaccine subcutaneously in horses. Do not inject the vaccine intramuscularly in cats and dogs.

4.4 Special warnings for each target species

Do not vaccinate unhealthy animals

4.5 Special precautions for use

(i) Special precautions for use in animals:
Where a dog or 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.
Where horses, cattle or sheep were vaccinated before 4 months of age, the primary vaccination scheme should be completed by an injection given at 4 months 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 interactions

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 vaccine 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 by subcutaneous or intramuscular route a 1-ml dose according to the following schedule:			
Species		Primary vaccination	Boosters
Dogs, cats		1 injection from 12 weeks of age.	1 year after primary vaccination, then at intervals of up to 3 years
Mustelids		1 injection from 12 weeks of age	Annual
Horses	Aged less than 6 months	1 injection from 4 months of age followed by a second injection 1 month later	Annual
	From 6 months of age	1 injection	Annual
Cattle, sheep	Aged less than 9 months	1 injection from 4 months of age followed by a second injection between 9 and 12 months of age	Annual
	From 9 months of age	1 injection	Annual

Administration to horses is by the intramuscular route only. Administration to cats and dogs is by the subcutaneous route only.

IE Pet Passport Procedure:
Animals intended for vaccination under the IE Pet Passport procedure 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 period(s)

Zero days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Inactivated vaccine in adjuvant against rabies
After administration, the vaccine stimulates active immunity against rabies
ATC Vet code: QI07AA02

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

GMEM medium
Protein hydrolysates
Salts

6.2 Major 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 products or waste materials derived from the use of such products

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(S)

VPA10454/074/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10 August 2004
Date of last renewal: 09 August 2009

10 DATE OF REVISION OF THE TEXT

July 2020