PACKAGE LEAFLET FOR:

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 Animal Health UK Ltd, Bracknell, RG12 8YS, UK

Boehringer Ingelheim Vetmedica GmbH, 55216 Ingelheim/Rhein, Germany

Manufacturer for the batch release
Boehringer Ingelheim Animal Health France SCS
Laboratoire Porte des Alpes
69 Saint-Priest
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rabisin – Suspension for Injection

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Each 1 ml dose of vaccine contains:

• Inactivated rabies virus, G52 strain		≥ 2.09 $\log_{10}$ OD_{50}* and ≥ 1 IU**
• Aluminium (as hydroxide)		1.7 mg
• 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

4. INDICATION(S)

For active immunisation of dogs and cats to reduce mortality and clinical signs due to rabies infection.
After administration, the vaccine stimulates active immunity against rabies. 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.

5. CONTRAINDICATIONS

Do not inject the vaccine intramuscularly.

6. ADVERSE REACTIONS

Vaccination may sometimes induce a local reaction, as s 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. If you notice any serious

effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs and Cats

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

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.

9. ADVICE ON CORRECT ADMINISTRATION

Administration is by the subcutaneous route only.

UK Pet Travel Scheme (PETS) and IE Pet Passport Procedure:
Animals intended for vaccination under the UK Pet Travel Scheme (PETS) and 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.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children

Store between +2°C and +8°C, protected from light. Do not freeze. Do not use after the expiry date stated on the label. Keep the container in the outer carton.

12. SPECIAL WARNING(S)

Do no vaccinate unhealthy animals
Can be used during pregnancy. 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.
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.
Do not mix with any other veterinary medicinal product. 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.
In the case of products administered parenterally, the products should be given at different sites.

No other signs than those described under the section 'Adverse reactions' have been observed after the administration of an overdose of vaccine.
In the case of accidental self-injection, seek medical advice immediately and show the package leaflet or label to the physician.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

April 2020

15. OTHER INFORMATION

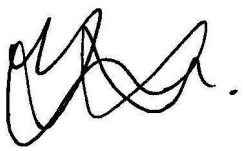
POM-V	POM

To be supplied only on veterinary prescription

Vm 08327/4150

IE: VPA10454/074/001

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



Approved: 12 October 2020