SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE IMMUNOLOGICAL VETERINARY PRODUCT

Vanguard Rabies

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

	Quantity/Dose
Active Constituents: Rabies Virus (Strain Flury LEP) (Inactivated, concentrated and purified rabies virus antigen	≥ 3.25 IU/ml of Rabies glycoprotein inducing ≥ 1.4 log10 IU/ml*
* Based on Ph. Eur. serology test)	
Adjuvant: Aluminium Hydroxide	1.7-2.1 mg

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Vanguard Rabies vaccine is a sterile opaque suspension for subcutaneous injection, with an off-white precipitate which readily resuspends on shaking.

4. CLINICAL PARTICULARS

4.1. Target species

Cats, dogs.

4.2. Indications for use, specifying the target species

For the active immunisation of cats and dogs to prevent infection and mortality due to rabies.
An antibody response normally develops within 7-14 days after vaccination. Vaccinated animals should not be exposed to the risk of rabies infection for 14 days. The specific immune response confers immunity for up to 3 years.

4.3. Contraindications

Do not use in unhealthy animals.
Do not use in pregnant animals.

4.4. Special warnings for each target species

None.

4.5. Special precautions for use

i) Special precautions for use in animals

Do not vaccinate animals for at least one month following the administration of immuno-suppressive drugs.

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

No special precautions apply.

4.6. Adverse reactions

As with all vaccines, occasional hypersensitivity may occur. In such cases, appropriate treatment, such as adrenalin, should be administered without delay.

In dogs, treatment with the vaccine produces oedematous swelling of up to 3.8 cm maximum diameter (5.4 cm^3 max. volume) at the site of injection. This swelling resolves with time and disappears by 21 days after treatment.

Treatment of cats with the vaccine produces a swelling of about 2-3 cm in diameter and raised by about 0.1 cm. at the site of injection. This swelling resolves with time and disappears by 24 hours after treatment. In some animals a fibrous nodule of 3 - 8 mm in diameter may develop at the site of injection 14 to 21 days after treatment. These nodules should resolve uneventfully over a period of 14 to 35 days.

4.7. Use during pregnancy and lactation

Do not use in pregnant animals

4.8. Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

4.9. Amounts to be administered and administration route

Cats and dogs: 1 mL by subcutaneous injection.

Vaccination Regime:
1 mL dose.

Cats and dogs may be vaccinated from 3 months of age and should be re-vaccinated every three years

4.10. Overdose

Cats: Treatment with a double dose of vaccine produces no systemic reaction. At the site of injection a swelling of about 2 - 3 cm in diameter and raised by about 0.2 cm occurs soon after treatment. This swelling disappears by 3 days after treatment. About 7 -21 days after treatment fibrous nodules may develop at the site of injection. These nodules should resolve uneventfully after a maximum of 35 days following their appearance.

Dogs: Treatment with a double dose of vaccine produces no systemic reaction. At the site of injection oedematous swelling of up to 4.5 cm maximum diameter (9 cm^3 max. volume) occurs soon after treatment. This swelling disappears by 28 days after treatment.

4.11. Withdrawal period

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

To stimulate active immunity against rabies.

ATCVet code: QI07AA02

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Aluminium hydroxide
Neomycin sulphate

6.2. Incompatibilities

Do not mix with any other vaccine/immunological product.

6.3. Shelf life

Shelf life of the veterinary medicinal product as package for sale: 3 years
Shelf life after first opening the immediate packaging: use immediately

6.4. Special precautions for storage

Store between +2° - +8°C.
Protect from light.
Do not freeze.

6.5. Nature and composition of immediate packaging

Single dose presentation (1mL) in a glass vial with bromobutyl rubber stopper and aluminium crimp seal. Printed cartons of 1 x 1 mL vial and 10 x 1 mL vials.
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 material derived from such products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
5th Floor, 6 St. Andrew Street
London
EC4A 3AE

8. MARKETING AUTHORISATION NUMBER

Vm 42058/4162

9. DATE OF FIRST AUTHORISATION

Date: 23 May 2000

10. DATE OF REVISION OF THE TEXT

Date: October 2015

Final information

In any animal population, there may be a number of individuals which fail to respond fully to vaccination. Successful vaccination depends upon the correct storage and administration of the vaccine together with the animal's ability to respond. This can be influenced by such factors as genetic constitution, intercurrent infection, age, the presence of maternally derived antibodies, nutritional status, concurrent drug therapy and stress.

Pet Travel Scheme (PETS)
Animals intended for vaccination under the Pet Travel Scheme (PETS) must be identified by a permanently numbered microchip. This microchip number must be recorded on the record of dog and cat vaccination at the time of rabies vaccination.

Approved: 02 September 2015