ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Vanguard Rabies – Outer Carton
1x 1ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vanguard Rabies

2. STATEMENT OF ACTIVE SUBSTANCES

Contains Flury LEP Rabies Virus grown on baby hamster kidney cells (BHK), chemically inactivated and adsorbed on aluminium hydroxide.
Each 1ml dose contains ≥ 3.25 IU/ml of Rabies glycoprotein inducing ≥ 1.4 $\log_{10}$ IU/ml

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

1 x 1ml single dose vial

5. TARGET SPECIES

Rabies vaccine for cats and dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Important:
Read the package leaflet before use

Dose:
1 ml
Give by subcutaneous injection only

8. WITHDRAWAL PERIOD(S)

Withdrawal Period:
Not applicable

9. SPECIAL WARNING(S), IF NECESSARY

Directions:
See enclosed package leaflet

10. EXPIRY DATE

Exp:

11. SPECIAL STORAGE CONDITIONS

Shake thoroughly before use.
Store between +2°C and +8°C.
Protect from light.
Do not freeze.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Any unused product or waste material should be disposed of in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

FOR ANIMAL TREATMENT ONLY

POM-V
To be supplied only on veterinary prescription

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

KEEP OUT OF REACH AND SIGHT OF CHILDREN.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4162

17. MANUFACTURER'S BATCH NUMBER

Batch No:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vanguard Rabies – Vial Label
1 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vanguard Rabies
Suspension for injection

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Rabies vaccine containing ≥ 3.25 IU/ml of Rabies glycoprotein inducing ≥ 1.4 $\log_{10}$ IU/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 ml (one dose)

4. ROUTE(S) OF ADMINISTRATION

For subcutaneous injection only.

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Batch No:

7. EXPIRY DATE

Exp.:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only
Vm 42058/4162 POM-V

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Vanguard Rabies

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vanguard Rabies
Suspension for injection

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

A sterile, opaque, fluid vaccine, with an off-white precipitate which readily resuspends on shaking. The vaccine contains a suspension of the Flury LEP (low egg passage) Rabies Virus, grown on baby Hamster Kidney Cells (BHK) in deep suspension, inactivated chemically, and adsorbed onto aluminium hydroxide as the adjuvant.
Each 1ml dose contains ≥ 3.25 IU/ml of Rabies glycoprotein inducing ≥ 1.4 $\log_{10}$ IU/ml*
*Based on Ph. Eur. serology test

4. INDICATION(S)

For the active immunisation of cats and dogs to prevent infection and mortality due to rabies.
The specific immune response confers immunity for up to 3 years.
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.

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

Local reaction at injection site following subcutaneous injection:

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.

Cats: 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.

Adverse reactions: Occasional hypersensitivity may occur. In such cases, appropriate treatment, such as adrenalin, should be administered without delay.

7. TARGET SPECIES

Cats, dogs.

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

1 ml by subcutaneous injection.
Shake the vial thoroughly before use.
Cats and dogs may be vaccinated from 3 months of age.
Cats and dogs should be re-vaccinated every three years.
NB. It should be remembered that local regulations may require a different re-vaccination schedule.
Use opened vials immediately.

9. ADVICE ON CORRECT ADMINISTRATION

Sterile syringes and needles must be used and the injection should be made through an area of clean, dry skin, taking aseptic precautions against contamination.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

KEEP OUT OF REACH AND SIGHT OF CHILDREN.
Store in a refrigerator (2°C – 8°C).
Protect from light. Do not freeze
Shelf life after first opening the immediate packaging: use immediately.

12. SPECIAL WARNING(S)

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

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.

Do not mix with any other veterinary medicinal product.

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

Any unused product or waste material should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

December 2014.

15. OTHER INFORMATION

FOR ANIMAL TREATMENT ONLY.

Legal category: POM-V
To be supplied only on veterinary prescription.

Package quantities: Packs containing 1 or 10 single dose vials. Not all pack sizes may be marketed.

Further information:
In safety trials, there were no systemic reactions seen.
In any animal population, there may be a small number of individuals which fail to respond fully to vaccination. Successful vaccination depends upon 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.

Marketing authorisation number:
Vm 42058/4162

Approved: 11/07/2017