PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Cardboard box (1 x 1 ml only) / Plastic Box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Versiguard Rabies suspension for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each dose (1 ml) contains:
Inactivated rabies virus min. 5 IU.

3. PACKAGE SIZE

1 x 1 ml
10 x 1 ml
10 x 10 ml

4. TARGET SPECIES

Dogs, cats, cattle, pigs, sheep, goats, horses and ferrets.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Dogs: SC.
Cats, ferrets, cattle, pigs, sheep, goats, horses: SC or IM.

7. WITHDRAWAL PERIODS

Withdrawal period: cattle, pigs, sheep, goats, horses: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 10 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator.
Do not freeze.

Protect from light.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited

14. MARKETING AUTHORISATION NUMBER

Vm 42058/5113

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V Veterinary medicinal product subject to prescription

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Glass vials (1 ml & 10 ml)}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT
Versiguard Rabies

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)
Inactivated rabies virus min. 5 IU/ml.

1 ml
10 ml

3. BATCH NUMBER
Lot {number}

4. EXPIRY DATE
Exp. {mm/yyyy}

5. ROUTE(S) OF ADMINISTRATION
SC/IM (dogs SC)

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”
For animal treatment only.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Versiguard Rabies suspension for injection

2. COMPOSITION

Each dose (1 ml) contains:

Active substance:

Inactivated rabies virus, strain SAD Vnukovo-32 ≥ 5 IU*
* IU – international units.

Adjuvant:

Aluminium hydroxide 2.0 mg.

Excipient:

Thiomersal 0.1 mg.

The visual appearance is as follows: slightly pink suspension, which might contain fine sediments.

3. TARGET SPECIES

Dogs, cats, cattle, pigs, sheep, goats, horses and ferrets.

4. INDICATIONS FOR USE

For the active immunisation of dogs, cats, cattle, pigs, sheep, goats, horses and ferrets (12 weeks of age and older) to prevent infection and mortality caused by rabies virus.

Onset of immunity:
14–21 days after primary vaccination.

Duration of immunity:

Dogs: three years following the primary vaccination course.

Cats, cattle, pigs, sheep, goats, horses and ferrets: one year after primary vaccination, and two years after booster vaccinations.

5. CONTRAINDICATIONS

Do not use in animals that are showing signs of rabies or that are suspected of being infected with rabies virus.

Do not use in cases of hypersensitivity to the adjuvant or to any of the excipients.

6. SPECIAL WARNINGS

Special warnings:

Vaccinate healthy animals only.

Special precautions for safe use in the target species:

Not applicable

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

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

Pregnancy and lactation:

Can be used during pregnancy.

The vaccine has not been extensively tested in lactating animals. However, the limited data that are available indicate that administration of the vaccine to lactating animals will not be associated with an increased incidence of adverse reactions.

Interaction with other medicinal products and other forms of interaction:

Dogs

Safety and efficacy data are available which demonstrate that this vaccine can be administered subcutaneously in dogs on the same day as vaccines from the Vanguard range (Vanguard 7, Vanguard Plus 7, Vanguard Plus 5, Vanguard Plus 5L, Vanguard Pup, Vanguard Puppy, Vanguard CPV, Vanguard CPV +L, Vanguard DA2Pi, Vanguard DA2Pi+L, Vanguard Lepto ci where approved), either mixed or at different sites. The duration of immunity for the Vanguard range when used with Versiguard Rabies has not been established.

After concurrent or mixed administration of Versiguard Rabies and Vanguard canine range, vaccinated dogs may have a transient swelling (up to 6 cm) at the injection site and a transient swelling of the sub-mandibular and/or pre-scapular lymph nodes at the injection site 4 hours after vaccination. These signs resolve within 24 hours.

Safety and efficacy data are available which demonstrate that this vaccine can also be used as solvent for the live vaccines of the Versican Plus range (Versican Plus

DHPPi, DHP, DP, P and Pi) and administered subcutaneously in dogs. After mixed administration with the Versican Plus range vaccinated dogs may commonly have a transient swelling (up to 5 cm) at the injection site. The swelling can occasionally be painful, warm or reddened. Any such swelling will either have spontaneously resolved or be greatly diminished by 14 days after vaccination. In rare cases gastrointestinal signs such as diarrhoea and vomiting or anorexia and decreased activity are possible.

Use as solvent for the Versican Plus range:

The contents of a single vial of Versican Plus vaccine should be reconstituted with the contents of a vial containing 1 dose of Versiguard Rabies (instead of the solvent). Once mixed, the contents of the vial should appear a pink/red or yellowish colour with light opalescence. The mixed vaccines should be injected immediately via the subcutaneous route.

Co-administration with Vanguard canine range:

To mix both products, Vanguard vaccines should be reconstituted according to their SPCs. The reconstituted vial will be well shaken and then mixed with 1 ml of Versiguard Rabies either in the Versiguard Rabies vial or the syringe. Versiguard Rabies will be well shaken before use. The mixed vaccines will be gently shaken and then administered immediately by subcutaneous injection.

Other target species

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.

Overdose:

Local reactions after subcutaneous vaccination with an overdose tended to larger (up to 12 mm in diameter) than after a standard dose.

Special restrictions for use and special conditions for use:

National rabies control legislation may require different vaccination programmes to that recommended in section “Dosage for each species, routes and method of administration” (e. g., more frequent vaccination) or may restrict rabies vaccination to particular target species.

Official control authority batch release is required for this product.

Major incompatibilities:

Do not mix with any other veterinary medicinal product except those mentioned in section “Interaction with other medicinal products and other forms of interaction” above.

7. ADVERSE EVENTS

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Injection site swelling[1] Hypersensitivity reaction[2]

[1]Transient, following subcutaneous administration which may reach up to 10 mm in diameter and in rare cases be associated with mild discomfort. Usually resolves within 10 days.
[2]Appropriate treatment should be administered without delay.

Cats, cattle, pigs, sheep, goats, horses and ferrets:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Injection site pain[1], Injection site swelling[2] Hypersensitivity reaction[3]

[1]Mild and associated with injection site swelling.
[2]Transient.

- following intramuscular administration may reach up to 2 cm in diameter and usually resolves within 7 days.
- following subcutaneous administration may reach up to 10 mm in diameter and usually resolves within 10 days. In rare cases may be associated with mild discomfort.

[3]Appropriate treatment should be administered without delay.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dogs: administer by subcutaneous injection.
All other species: administer by subcutaneous or intramuscular injection.

Dosage:
A single dose of 1 ml is sufficient irrespective of age, weight or animal species.

Primary vaccination scheme:
Animals of all target species can be vaccinated from 12 weeks of age.
Primary vaccination is with a single dose of vaccine.

Re-vaccination scheme:

Dogs: a single dose of Versiguard Rabies should be given every 3 years. Antibody titres drop over the course of the 3-year duration of immunity, although dogs are protected when challenged. In case of travelling to risk areas or outside the UK, veterinary surgeons may wish to give additional rabies vaccinations to ensure that the vaccinated dogs have an antibody titre ≥ 0.5 IU/ml, which is generally regarded as sufficiently protective and that they meet the travel test requirements (antibody titres ≥ 0.5 IU/ml).

Cats, cattle, pigs, sheep, goats, horses and ferrets: animals should be revaccinated with one dose of vaccine 1 year after primary vaccination.
After the first booster vaccination (administered 1 year after primary vaccination), animals should be revaccinated every 2 years with one dose of vaccine.

9. ADVICE ON CORRECT ADMINISTRATION

Shake the vial before use.

10. WITHDRAWAL PERIODS

Dogs, cats, ferrets: Not applicable.
Cattle, pigs, sheep, goats, horses: Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store in a refrigerator (2 °C – 8 °C).

Do not freeze.

Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: 10 hours.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.

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

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBER AND PACK SIZES

Vm 42058/5113

The vaccine is supplied in type I (1 ml or 10 ml) glass vials complying with Ph. Eur., sealed with a bromobutyl rubber stopper and aluminium cap.

Cardboard box of 1 vial of 1 ml.
Plastic box of 10 vials of 1 ml or 10 ml.

Not all pack sizes may be marketed.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

November 2023

Find more product information by searching for ‘Product Information Database’ or ‘PID’ on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder and contact details to report suspected adverse reactions:

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP
Tel: +44 (0) 345 300 8034

Manufacturer responsible for batch release:
Bioveta a.s.
Komenskeho 212/12
683 23 Ivanovice Na Hane
Czechia

17. OTHER INFORMATION

The vaccine stimulates active immunity in the target species against rabies.

As required by the European Pharmacopoeia, efficacy was demonstrated by challenge in dogs and cats, and by serology in the other target species. One year after primary vaccination, 100% of dogs and cats vaccinated via either the subcutaneous or intramuscular routes were protected against challenge. Two years after booster vaccination, protection rates against challenge were 92% of cats vaccinated via either the subcutaneous or intramuscular routes. Three years after primary vaccination, 96% of dogs vaccinated by subcutaneous route were protected against challenge. Protection rates against challenge in dogs and cats, and serology results for the other target species, comply with the efficacy criteria of the European Pharmacopoeia for inactivated rabies vaccine at both the one-year, two-year and three-year assessments.

POM-V
Veterinary medicinal product subject to prescription

For animal treatment only.

Approved 06 November 2023