

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Versiguard Rabies suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose (1 ml) contains:

Active substance:

Inactivated rabies virus, strain SAD Vnukovo-32 min. 2.0 IU*
* IU – international units

Adjuvant:

Aluminium hydroxide 2.0 mg

Excipients:

Thiomersal 0.1 mg.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.

Slightly pink solution, which might contain fine sediments.

4. CLINICAL PARTICULARS

4.1 Target species

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

4.2 Indications for use, specifying the target species

For the active immunization 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: At least three years following the primary vaccination course.

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

4.3 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.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals

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.

4.6 Adverse reactions (frequency and seriousness)

A transient swelling may occur at the injection site following subcutaneous administration in all target species in very rare cases. The swelling may reach a maximum diameter of up to 10 mm, and in rare cases be associated with mild discomfort. These reactions usually resolve within 10 days.

Transient mild pain (which in rare cases may be associated with swelling) at the site of injection following intramuscular administration in any other target species than dogs may very rarely occur. The swelling may reach a maximum diameter of up to 2 cm. These reactions usually resolve within 7 days.

Hypersensitivity reactions may occur very rarely. If such a reaction occurs, appropriate treatment should be administered without delay.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

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.

4.8 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 any other vaccine 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.

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.

4.9 Amounts to be administered and administration route

Dogs: Administer by subcutaneous injection.

All other species: Administer by subcutaneous or intramuscular injection.

Shake the vial before use.

Dosage:

A single dose inoculation of 1 ml is sufficient irrespective of age, weight or breed of animal.

Primary vaccination:

Animals of all target species can be vaccinated from 12 weeks of age.

Primary vaccination is with a single dose of vaccine.

Revaccination:

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 EU, 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.

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 single vial of Versiguard Rabies (instead of the solvent). Once mixed, the contents of the vial should appear a pink/red or yellowish colour with a slight 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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

4.11 Withdrawal period

Dogs, cats, ferrets: Not applicable.

Cattle, pigs, sheep, goats, horses: Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: immunologicals for Canidae, inactivated viral vaccines for dogs.
ATCvet code: QI07AA02.

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Thiomersal

Aluminium hydroxide (as 2% of aluminium hydroxide gel)

Water for injections

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product other than vaccines of the Vanguard range containing CDV, CAV, CPV, CPiV and *Leptospira* or Versican Plus range containing CDV, CAV, CPV and/or CPiV.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

Shelf life after first opening the immediate packaging: 10 hours.

6.4. Special precautions for storage

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

Do not freeze.

Protect from light.

6.5 Nature and composition of immediate packaging

The vaccine is supplied in type I (1 ml, 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.

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 materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

To be completed nationally

8. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

To be completed nationally

10 DATE OF REVISION OF THE TEXT

To be completed nationally

PROHIBITION OF SALE, SUPPLY AND/OR USE

National rabies control legislation may require different vaccination programmes to that recommended in section 4.9 (e. g., more frequent vaccination) or may restrict rabies vaccination to particular target species.

