SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Canigen Rabies Suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml dose contains:

Active substance:
Inactivated rabies virus strain Pasteur RIV: ≥ 0.95 AIU* equivalent to ≥ 2 IU**

** Batch control is performed with an in vitro potency test according to Ph. Eur. monograph 451. AIU = rabies antigenic mass AlphaLISA International Units.*

*** Corresponding potency in the in vivo mouse challenge test according to Ph. Eur. Monograph 451.*

Adjuvant:
Aluminium phosphate (adjuvant) 0.60 - 0.88 mg Al^{3+}

Excipients:
Thiomersal (preservative) 0.1 mg

For the full list of excipients see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection

Light yellow/orange to slightly red/purple with a whitish sediment.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs and cats.

4.2 Indications for use, specifying the target species

For the active immunisation against rabies to reduce clinical signs and mortality.

Onset of immunity: an adequate serological response (≥ 0.5 IU) has been demonstrated 2 to 3 weeks after vaccination.
Duration of immunity: 3 years.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

The vaccine may not be effective in animals incubating the disease at the time of vaccination.

Some animals may be immunologically incompetent and fail to respond to vaccination. A good immune response is reliant on the reaction of an immunogenic agent and a fully competent immune system. Immunocompetence of the animal may be compromised by a variety of factors including poor health, nutritional status, genetic factors, concurrent drug therapy and stress.

4.5 Special precautions for use

Special precautions for use in animals
The presence of maternal antibodies can interfere with the response to vaccination.

This product should not be administered for at least one month following the administration of hyperimmune serum (anti-serum) or immunosuppressant drugs.

Immunogenicity of the vaccine antigen will be reduced by poor storage or inappropriate administration.

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

Transient local reactions such as non-painful diffuse to firm swellings of approximately 1 cm in diameter may be observed for up to 3 weeks after subcutaneous vaccination.

A transient acute hypersensitivity reaction - with signs that may include, facial oedema, vomiting, pruritus or diarrhoea - may occur shortly after vaccination in very rare cases. Such reactions may evolve to a more severe condition (anaphylaxis), which may be life-threatening with additional signs like dyspnoea, collapse, ataxia, muscle tremor and convulsion. If such reactions occur appropriate treatment is recommended.

Clinical signs of immune-mediated haemolytic anaemia, immune-mediated thrombocytopenia or immune-mediated polyarthritis have been reported in very rare cases.

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 and lactation

Pregnancy:
Can be used during pregnancy in dogs. There are no laboratory data on use during pregnancy in other species, but on basis of field experience, such use is expected to be safe.

4.8 Interactions with other medicinal products and other forms of interaction

Safety and efficacy data are available which demonstrate that this vaccine can be mixed and administered with vaccines in the Canigen range containing one or more of the following components: live canine distemper, canine adenovirus, canine parvovirus and canine parainfluenza or live feline viral rhinotracheitis virus, feline calicivirus and feline panleucopenia virus.

Safety and efficacy data are available which demonstrate that Canigen Rabies can be administered on the same day but not mixed with Canigen vaccines containing canine *Leptospira interrogans* serogroups Canicola and Icterohaemorrhagiae antigens.

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 made on a case by case basis.

4.9 Amount to be administered and administration route

Administer a dose of 1 ml irrespective of the size, species or breed of animal.

Intramuscular or subcutaneous use.

Sterile equipment should be used for administration. Avoid contamination of vaccine with traces of chemical sterilising agents. Do not use chemicals such as disinfectant or spirit to disinfect the skin prior to inoculation.

Primary course and booster vaccination in dogs and cats

Primary vaccination age*	12 weeks or older
Booster vaccination	every 3 years

*The primary vaccination may be administered at an earlier age, but a second dose must then be administered at the age of 12 weeks.
Minimum vaccination age in dogs and cats: 4 weeks.

Further information
Limited safety data for ferrets are available from monitoring post vaccination reactions. Ferrets can be vaccinated subcutaneously from 12 weeks of age.

An adequate serological response (≥ 0.5 IU) has been demonstrated 1 month after vaccination.
Ferrets should receive a booster vaccination every 18 months.

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

No effects other than those in section 4.6.

4.11 Withdrawal period(s)

Not applicable

5. IMMUNOLOGICAL PROPERTIES

ATCvet code: QI07AA02

The vaccine contains inactivated antigens to stimulate active immunity against rabies.

6. PHARMACEUTICAL PRECAUTIONS

6.1 List of excipients

Aluminium phosphate
Disodium hydrogen phosphate dihydrate
Sodium dihydrogen phosphate dihydrate
Thiomersal
Water for injections

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal products except components recommended for use with the veterinary medicinal product listed in section 4.8

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 4 years.

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

Type I glass vial closed with rubber stopper and aluminium cap.

Package sizes:
Cardboard box with 1 x 1 ml, 10 x 1 ml or 50 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, if appropriate

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

7. MARKETING AUTHORISATION HOLDER

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 06376/4109

9. DATE OF FIRST AUTHORISATION

25 October 2005

10. DATE OF REVISION OF THE TEXT

December 2024

Gavin Hall
Approved: 19 December 2024