SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Canigen Parvo-C lyophilisate for suspension for injection for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml dose contains:
Active substance:
Live canine parvovirus (CPV), strain 154 $\geq 10^{7.0}$ $TCID_{50}$*
*Tissue culture infective dose 50%

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate for suspension for injection.

Lyophilisate: off-white or cream-coloured pellet.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, including target species

For active immunisation of dogs to prevent mortality, clinical signs and viral excretion following canine parvovirus infection.

Onset of immunity: 1 week.
Duration of immunity: 3 years.

4.3 Contraindications

None.

4.4 Specific warnings for each target species

Vaccinate healthy animals only.

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

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

The vaccine has been proved to be of benefit against virulent challenge in the presence of maternal antibody levels to CPV that are likely to be encountered under field conditions.

Experience has shown that the maternal antibody status of pups within a litter varies greatly, and reliance should not be placed on serological examination of the bitch alone.

4.5 Special precautions for use

Special precautions for use in animals:
Animals that have received a corresponding anti-serum or immunosuppressive drugs should not be vaccinated until an interval of at least 4 weeks has elapsed.

Vaccinated dogs may excrete the parvovirus vaccine strain at very low levels for up to 8 days after vaccination. However, there is no evidence of any reversion to virulence of the vaccine strain and therefore no need to separate unvaccinated dogs from contact with recently vaccinated dogs.

Special precautions to be taken by the person administering the 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 diffuse swelling, up to 5 mm in diameter, may commonly be observed at the site of injection. Occasionally this swelling may be hard and painful and last for up to 3 days post injection.

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

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, including isolated reports).

4.7 Use during pregnancy and lactation

Pregnancy:
Can be used in pregnant bitches which have previously been vaccinated with the CPV (strain 154) antigens included in the Canigen vaccine range.

4.8 Interaction 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 the inactivated vaccines in the Canigen range for subcutaneous administration against canine leptospirosis caused by all or some of the following serovars: *L. interrogans* serogroup Canicola serovar Canicola, *L. interrogans* serogroup Icterohaemorrhagiae serovar Copenhageni, *L. interrogans* serogroup Australis serovar Bratislava, and *L. kirschneri* serogroup Grippotyphosa serovar Bananal/Liangguang.

After administration with one of the leptospirosis vaccines, a mild and transient increase in body temperature (≤ 1 °C) may occur for a few days after vaccination, with some pups showing less activity and/or a reduced appetite. A small transient swelling (≤ 4 cm), which can occasionally be firm and painful on palpation, may be observed at the site of injection. Any such swelling will either have disappeared or be clearly diminished by 14 days post-vaccination.

After mixed administration of an overdose of Canigen Parvo-C and an overdose of the leptospirosis vaccines in the Canigen range, transient local reactions such as diffuse to firm swellings from 1 to 5 cm in diameter may be observed, usually these will persist no longer than 5 weeks, however some may take a little longer to completely disappear.

Safety and efficacy data are available which demonstrate that this vaccine can be mixed and administered with the inactivated vaccine in the Canigen range against rabies. After administration with the rabies vaccine, where this product is authorised, transient local reactions such as diffuse to firm swellings from 1 to 4 cm in diameter may be observed for up to 3 weeks after vaccination. The swellings may be painful for up to 3 days post dosing.

Safety and efficacy data are available which demonstrate that this vaccine can be administered at the same time but not mixed with the inactivated vaccine in the Canigen range against *Bordetella bronchiseptica*.

Product information of the relevant Canigen vaccines should be consulted before mixed product administration.

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 Amounts to be administered and administration route

Reconstitute the vaccine with 1 ml solvent or 1 ml (1 dose) of the inactivated vaccines listed in section 4.8.

Subcutaneous use.

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.

Maternal antibodies can negatively interfere with the efficacy of a vaccine. Strict adherence to the vaccination programme is therefore recommended.

Vaccination programme:
Primary vaccination course:
A single injection should establish active immunity to disease caused by canine parvovirus infection in dogs of 10 weeks of age or older. Where earlier protection is required a first dose may be given to puppies from 4 weeks of age, but because maternally derived passive antibody can interfere with the response to vaccination a final dose at 10 weeks of age or older is generally recommended.

Booster vaccination:
It is recommended that dogs be revaccinated against canine parvovirus every 3 years.

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

No effects other than those indicated in section 4.6. In some dogs the swelling may be more painful or may be observed for a longer period.

4.11 Withdrawal periods

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for *Canidae*; live viral vaccines for dogs
ATCvet code: QI07AD01

The vaccine contains attenuated antigens to stimulate active immunity against canine parvovirus disease.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitol
Hydrolysed gelatin
Pancreatic digest of casein

Disodium phosphate dihydrate
Water for injections.

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product except solvent supplied for use with the veterinary medicinal product or the Canigen dog vaccines mentioned in section 4.8.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after reconstitution according to directions: 30 minutes.

6.4 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).
Do not freeze.
Protect from light.

Care should be taken to avoid prolonged or repetitive exposure to high ambient temperatures following withdrawal from the refrigerator prior to use - in hot summer conditions vaccine potency can be severely reduced within a few hours.

6.5 Nature and composition of immediate packaging

Type I (Ph. Eur.) clear glass single dose vials with halogenobutyl rubber stopper, closed with a colour coded aluminium cap.

Pack sizes:
Cardboard or plastic boxes containing 10 x 1 or 50 x 1 dose vials.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused 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

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

8. MARKETING AUTHORISATION NUMBER

Vm 06376/4108

9. DATE OF FIRST AUTHORISATION

1 August 2007

10. DATE OF REVISION OF THE TEXT

December 2024

Gavin Hall
Approved: 19 December 2024