SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Canigen Pi Lyophilisate and solvent for suspension for injection for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml dose of reconstituted vaccine contains:
Active substance:
Live attenuated canine parainfluenza virus (CPi) strain Cornell: ≥ $10^{5.5}$ and ≤ $10^{7.3}$ $TCID_{50}$*.

*$TCID_{50}$ = median Tissue Culture Infective Dose

Solvent (1 ml per vial):
Phosphate buffered saline.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

Lyophilisate: Off-white or cream-coloured pellet.
Solvent: clear colourless solution.

Reconstituted product: off-pink or pink suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the target species

For active immunisation of dogs from the age of 8 weeks onward to reduce clinical signs of canine para-influenza infection and to reduce viral shedding.

Onset of immunity: 4 weeks after vaccination.
Duration of immunity: has not been demonstrated, but an anamnestic response is produced in dogs given a revaccination one year after basic vaccination.

4.3 Contraindications

None.

4.4 Specific warnings for each target species

A protective antibody titre is not accomplished in all vaccinated dogs.

As maternally derived passive antibodies can interfere with the response to vaccination in very young animals, a final dose at 10 weeks of age or older is recommended.

4.5 Special precautions for use

Special precautions for use in animals:
Vaccinate only healthy dogs.
Sterile equipment should be used for administration

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 insert or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

In very rare cases, some dogs may show discomfort during injection.
In very rare cases, a diffuse swelling, up to 5 mm in diameter, may be observed at the site of injection; occasionally this swelling may be hard and painful and last for up to 3 days post injection.
In very rare cases, hypersensitivity reactions may occur. In the event of an anaphylactic reaction appropriate treatment such as adrenaline should be administered without delay.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Canigen Pi has been shown to be safe for use in pregnant bitches that have been vaccinated before pregnancy with the Pi vaccine of the Canigen range.

4.8 Interaction with other medicinal products and other forms of interaction

Safety and efficacy data (viral excretion) are available which demonstrate that this vaccine can be mixed and administered with the inactivated vaccines of the Canigen

range 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.

The product information of the relevant Canigen vaccines should be consulted before administration of the mixed product. When mixed with Canigen leptospirosis vaccines at annual revaccination, it has been established that there is no interference with the anamnestic response induced by the injectable canine parainfluenza virus component.

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 Pi 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 or the inactivated vaccine against rabies and leptospirosis, where applicable. After administration with the rabies containing vaccines 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 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*.

When this vaccine is administered in association with the inactivated vaccine in the Canigen range against *Bordetella bronchiseptica*, the demonstrated antibody response data of this vaccine are the same as when this vaccine is administered alone.

When Canigen Pi is used with any of the other Canigen vaccines referred to above, the minimum vaccination age for each vaccine must be taken into account such that at the time of vaccination, the dogs are at or older than the oldest minimum vaccination age for the individual vaccines.

No information is available on the compatibility 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

One ml (1 ml) solvent or 1 ml (1 dose) of inactivated vaccine (as specified in section 4.8) must be used to reconstitute the freeze-dried Canigen Pi vaccine.
One dose (1 ml) of the reconstituted vaccine should be administered by subcutaneous injection.

Vaccination schedule:
Basic vaccination:

- Before the age of 12 weeks:

Two vaccinations, each with a single dose: the first vaccination from the age of 8 weeks onwards and the second vaccination 2 – 4 weeks later.

- From the age of 12 weeks onwards:

A single vaccination, with one dose per animal

Revaccination:
Every year with a single dose.

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

Not different from a single dose. In some dogs the swelling may be more painful or may be observed for a longer period.

4.11 Withdrawal period(s)

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for *Canidae*, live viral vaccines for dogs.
ATCvet code: QI07AD08.

Induction of active immunity against canine parainfluenza virus.
Under laboratory conditions, antibody response, reduction of clinical signs and/or reduction of virus excretion have been observed after challenge with CPi virus 4 weeks after vaccination.
It was not possible to produce clinical signs by CPi challenge in adult dogs and duration of immunity could therefore not be demonstrated, but an anamnestic response was seen in dogs given a revaccination one year after basic vaccination.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lyophilisate:
Sorbitol
Hydrolysed gelatin
Pancreatic digest of casein
Disodium phosphate dihydrate

Solvent:
Disodium phosphate dihydrate
Potassium dihydrogen phosphate
Water for injections.

6.2 Major Incompatibilities

Do not mix with any other veterinary medicinal product, except the Canigen dog vaccines mentioned in section 4.8 (where these products are authorised).

6.3 Shelf- life

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

Solvent:
Shelf-life of the solvent: 4 years.

6.4 Special precautions for storage

Vaccine:
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.

Solvent:
Store below 25 °C if stored independently from the vaccine.

6.5 Nature and contents of container

Vaccine:
Vial of hydrolytical class type I (Ph. Eur.) glass closed with a halogenobutyl rubber stopper and aluminium cap.

Solvent:
Vial of hydrolytical class type I (Ph. Eur.) glass closed with a halogenobutyl rubber stopper and aluminium cap.

Pack sizes:
Carton or plastic box with 5, 10, 25 or 50 single dose vials.
The solvent may be packed with the vaccine or separately.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused medicinal product or waste materials, if any

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 06376/4116

9. DATE OF FIRST AUTHORISATION

26 August 2003

10. DATE OF REVISION OF THE TEXT

November 2024

Approved 18 November 2024
Gavin Hall