ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Canigen puppy 2b suspension for injection (BE CZ ES HU IT LU NL PT SK)

Virbagen Puppy 2b suspension for injection (AT DE)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (1 ml) contains

Active substance:
Live attenuated canine parvovirus 2b strain CPV39: $10^{5.6}$ to $10^{7.5}$ $CCID_{50}$*
* Cell culture infectious dose 50%.

Excipients:

Qualitative composition of excipients and other constituents
Sodium chloride
Potassium dihydrogen phosphate
Disodium phosphate
Water for injections

Colourless suspension.

3. CLINICAL INFORMATION

3.1 Target species

Dog (puppy)

3.2 Indications for use for each target species

For active immunisation of dogs against canine parvovirosis, to reduce virus excretion, to prevent mortality and typical signs (enteric form) from the age of 5 weeks.

Onset of immunity: Two weeks after vaccination.
Duration of immunity: Until the age of 11 weeks.

3.3 Contraindications

None.

3.4 Special warnings

The vaccinal strain can spread. It has been demonstrated that this spread did not cause adverse effects on pregnant or lactating females or cats.
Animals have to be treated for intestinal endoparasites prior to vaccination.

In the case of high levels of maternal derived antibodies (>1/80) the seroconversion rate is reduced from 94% to 42%.

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:

The vaccine should be administered in accordance with the usual aseptic conditions for vaccination.

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

The active ingredient of the vaccine is non-pathogenic for man but normal precautions should be taken to avoid contact with the skin and mucosa and self-injection.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Dog (puppy)

Very common (>1 animal / 10 animals treated):	Injection site pruritus[1,2,3] Injection site pain[1,2] Injection site swelling[1,4]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hypersensitivity reaction[5]

[1]Slight transitory.
[2]May appear up to 30 minutes after vaccination.
[3]Lasting less than 1 minute
[4]Disappearing spontaneously within 2-3 hours after occurrence.
[5] In case of anaphylactic shock, appropriate symptomatic treatment should be administered without delay.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Do not use during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

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.

3.9 Administration routes and dosage

Administer one dose of 1ml of the veterinary medicinal product subcutaneously to 5 week old puppies**.**
Due to the heterogeneous distribution of maternal antibodies among puppies a second injection of a 1 ml dose two weeks later is recommended. To ensure a long term protection, a conventional vaccination scheme with a vaccine containing a canine parvovirus valence should be carried out starting before the age of 11 weeks.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

After a ten-fold overdose of the maximum authorized release titre, no other adverse effects were osberved than those mentioned in section 3.6.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI07AD01

The active substance of the vaccine is an attenuated live canine parvovirus type 2b strain to stimulate active immunity against enteric form of parvovirosis in puppies from 5 weeks of age. It induces the development of specific antibodies against CPV serotypes –2b, -2a, -2.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

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

5.3. Special precautions for storage

Store and transport refrigerated between 2°C and 8°C.
Do not freeze.
Protect from light.

5.4 Nature and composition of immediate packaging

Vial (glass, type I) of 3 ml for injectable preparations with elastomer stopper containing 1 ml of vaccine.
The product is presented in boxes of 10 or 50 vials.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

VIRBAC

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

10 or 50 UNIT BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Canigen puppy 2b suspension for injection (BE CZ ES HU IT LU NL PT SK)

Virbagen Puppy 2b suspension for injection (AT DE)

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (1 ml) contains:

Active substance:

Live attenuated canine parvovirus 2b strain CPV39 $10^{5.6}$ to $10^{7.5}$ $CCID_{50}$*

* Cell culture infectious dose 50%.

3. PACKAGE SIZE

10 x 1 ml
50 x 1 ml

4. TARGET SPECIES

Dog (puppy)

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
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

VIRBAC

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1 ml vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Canigen puppy 2b (BE CZ ES HU IT LU NL PT SK)

Virbagen Puppy 2b (AT DE)

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Parvovirus 2b
1 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Canigen puppy 2b suspension for injection (BE CZ ES HU IT LU NL PT SK)

Virbagen Puppy 2b suspension for injection (AT DE)

2. Composition

Each dose (1 ml) contains:

Active substance:

live attenuated canine parvovirus 2b strain CPV39 $10^{5.6}$ to $10^{7.5}$ $CCID_{50}$*

* Cell culture infectious dose 50%.

Colourless suspension.

3. Target species

Dog (puppy)

4. Indications for use

For active immunisation of dogs against canine parvovirosis, to reduce virus excretion, to prevent mortality and typical signs (enteric form) from the age of 5 weeks.
Onset of immunity: Two weeks after vaccination.
Duration of immunity: Until the age of 11 weeks.

5. Contraindications

None.

6. Special warnings

Special warnings:

The vaccinal strain can spread. It has been demonstrated that this spread did not cause adverse effects on pregnant or lactating females or cats.
Animals have to be treated for intestinal endoparasites prior to vaccination.
In the case of high levels of maternal derived antibodies (>1/80) the seroconversion rate is reduced from 94% to 42%.
Vaccinate healthy animals only.

Special precautions for safe use in the target species:

The vaccine should be administered in accordance with the usual aseptic conditions for vaccination.

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

The active ingredient of the vaccine is non-pathogenic for man but normal precautions should be taken to avoid contact with the skin and mucosa and self-injection.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation:

Do not use during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:

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:

After a ten-fold overdose of the maximum authorized release titre, no other adverse effects were osberved than those mentioned in section 3.6.

Major incompatibilities:

Do not mix with any other veterinary medicinal product.

7. Adverse events

Dog (puppy).

Very common (> 1 animal / 10 animals treated):
Injection site pruritus[1,2,3] Injection site pain[1,2] Injection site swelling[1,4]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Hypersensitivity reaction[5]

[1]Slight transitory.
[2]May appear up to 30 minutes after vaccination.
[3]Lasting less than 1 minute
[4]Disappearing spontaneously within 2-3 hours after occurrence.
[5]In case of anaphylactic shock, appropriate symptomatic 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 or the local representative of 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

Administer one dose of 1ml of the product subcutaneously to 5 week old puppies**.**

Due to the heterogeneous distribution of maternal antibodies among puppies a second injection of a 1 ml dose two weeks later is recommended.

9. Advice on correct administration

To ensure a long term protection, a conventional vaccination scheme with a vaccine containing a parvovirus valence should be carried out starting before the age of 11 weeks.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of reach and sight of children.

Store and transport refrigerated between 2°C and 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. The expiry date refers to the last day of that month

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vial (glass, type I) of 3 ml for injectable preparations with elastomer stopper containing 1 ml of vaccine.
The product is presented in boxes of 10 or 50 vials.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).

16. Contact details

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

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

Manufacturer responsible for batch release:

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

Local representative(s) and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.