ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box of 1 or 10 vials of lyophilisate and 1 or 10 vials of suspension

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CANIXIN DHPPi/L lyophilisate and suspension for suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 1 ml contains:

Active substances

Lyophilisate

Live attenuated canine distemper virus (CDV) - Lederle strain	$10^{3.0}$ - $10^{4.9}$ $CCID_{50}$*
Live attenuated canine adenovirus type 2 (CAV-2) - Manhattan strain	$10^{4.0}$ - $10^{6.0}$ $CCID_{50}$*
Live attenuated canine parvovirus (CPV) - CPV780916 strain	$10^{5.0}$ - $10^{6.8}$ $CCID_{50}$*
Live attenuated canine parainfluenza virus (CPiV) - Manhattan strain	$10^{5.0}$ - $10^{6.9}$ $CCID_{50}$*

* Cell culture infectious dose 50%

Suspension

Inactivated *Leptospira interrogans*:	
- serogroup Canicola serovar Canicola, strain 601903	4350 - 7330 U**
- serogroup Icterohaemorrhagiae serovar Icterohaemorrhagiae, strain 601895	4250 - 6910 U**

** Antigenic mass ELISA units

3. PACKAGE SIZE

1 x 1 dose lyophilisate and 1 x 1 mL suspension
10 x 1 dose lyophilisate and 10 x 1 mL suspension

4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Protect from light.
Do not freeze.

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

Vm 05653/3023

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box of 25, 50 or 100 vials of lyophilisate and 25, 50 or 100 vials of suspension

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CANIXIN DHPPi/L lyophilisate and suspension for suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose of 1 ml contains:

Active substances

Lyophilisate

Live attenuated canine distemper virus (CDV) - Lederle strain	$10^{3.0}$ - $10^{4.9}$ $CCID_{50}$*
Live attenuated canine adenovirus type 2 (CAV-2) - Manhattan strain	$10^{4.0}$ - $10^{6.0}$ $CCID_{50}$*
Live attenuated canine parvovirus (CPV) - CPV780916 strain	$10^{5.0}$ - $10^{6.8}$ $CCID_{50}$*
Live attenuated canine parainfluenza virus (CPiV) - Manhattan strain	$10^{5.0}$ - $10^{6.9}$ $CCID_{50}$*

* Cell culture infectious dose 50%

Suspension

Inactivated *Leptospira interrogans*:	
- serogroup Canicola serovar Canicola, strain 601903	4350 - 7330 U**
- serogroup Icterohaemorrhagiae serovar Icterohaemorrhagiae, strain 601895	4250 - 6910 U**

** Antigenic mass ELISA units

3. PACKAGE SIZE

25 x 1 dose lyophilisate and 25 x 1 mL suspension
50 x 1 dose lyophilisate and 50 x 1 mL suspension
100 x 1 dose lyophilisate and 100 x 1 mL suspension

4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use immediately.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Protect from light.
Do not freeze.

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

Vm 05653/3023

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial with lyophilisate

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CANIXIN DHPPi/L

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

DHPPi
1 dose

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial with suspension

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CANIXIN DHPPi/L

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

L
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

CANIXIN DHPPi/L lyophilisate and suspension for suspension for injection for dogs

2. Composition

Each dose of 1 ml contains:

Active substances

Lyophilisate

Live attenuated canine distemper virus (CDV) - Lederle strain	$10^{3.0}$ - $10^{4.9}$ $CCID_{50}$*
Live attenuated canine adenovirus type 2 (CAV-2) - Manhattan strain	$10^{4.0}$ - $10^{6.0}$ $CCID_{50}$*
Live attenuated canine parvovirus (CPV) - CPV780916 strain	$10^{5.0}$ - $10^{6.8}$ $CCID_{50}$*
Live attenuated canine parainfluenza virus (CPiV) - Manhattan strain	$10^{5.0}$ - $10^{6.9}$ $CCID_{50}$*

* Cell culture infectious dose 50%

Suspension

Inactivated *Leptospira interrogans*:	
- serogroup Canicola serovar Canicola, strain 601903	4350 - 7330 U**
- serogroup Icterohaemorrhagiae serovar Icterohaemorrhagiae, strain 601895	4250 - 6910 U**

** Antigenic mass ELISA units

Lyophilisate: White lyophilisate
Suspension: Translucent liquid

3. Target species

Dogs.

4. Indications for use

For active immunisation of dogs from 8 weeks of age to:
- prevent mortality and clinical signs caused by CDV;
- prevent mortality and clinical signs caused by canine adenovirus type 1 (CAV-1);
- prevent clinical signs and mortality and reduce excretion caused by CPV in challenge studies performed with a CPV-2b strain;
- prevent clinical signs and reduce excretion caused by CPV in a challenge study performed with a CPV-2c strain;

- reduce respiratory clinical signs and viral excretion caused by CPiV and CAV-2;
- prevent mortality and reduce infection, clinical signs, kidney colonisation, renal lesions and urine shedding of *L.* Canicola;
- reduce infection, clinical signs, kidney colonisation and urine shedding of *L.* Icterohaemorrhagiae;

Onset of immunity:
The onset of immunity has been demonstrated from 3 weeks after the primary vaccination for CDV, CAV-2 and CPV, 4 weeks for CAV-1 and CPiV, 5 weeks for *L.* Canicola and 2 weeks for *L.* Icterohaemorrhagiae.

Duration of immunity:
After the primary vaccination course, the duration of immunity lasts for one year for all components.
In the duration of immunity studies one year after the basic vaccination scheme there was no significant difference between vaccinated and control dogs in viral excretion for CPiV and CAV-2, in reduction of kidney colonisation for *L.* Canicola and *L.* Icterohaemorrhagiae, nor in renal lesions and urine shedding for *L.* Canicola.
After the annual booster, the duration of immunity lasts for 3 years for CDV, CAV-1, CAV-2 and CPV.
For CAV-2, the duration of immunity after the annual booster was not established by challenge, and is based on the presence of CAV-2 antibodies 3 years after the booster vaccination.

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.
The presence of maternally derived antibodies (puppies from vaccinated females) may in some cases interfere with the vaccination. Therefore the vaccination scheme should be adapted accordingly (see section “Dosage for each species, routes and method of administration”).

Special precautions for safe use in the target species:
After vaccination, the live viral vaccinal strains (CAV-2, CPV) can be spread to unvaccinated animals without any pathological effect for these in-contact animals.

Special precautions to be taken by the person administering the veterinary 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.

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:
The administration of a 10 fold overdose at a single injection site did not cause any reactions other than those mentioned in the section 'Adverse events' except that the duration of local reactions was increased (up to 26 days).

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. Adverse events

Dogs:

Common (1 to 10 animals / 100 animals treated):
Injection site swelling[1,2,3], Injection site oedema[2,3,4] Lethargy[2]
Rare (1 to 10 animals / 10,000 animals treated):
Injection site pain[2,3], Injection site pruritus (itching)[2,3] Hyperthermia[2], Anorexia[2] Digestive tract disorders[2] (e.g. Diarrhoea[2], Vomiting[2])
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Hypersensitivity reaction (e.g. Anaphylaxis (severe form of allergic reaction), Allergic skin reaction such as Allergic oedema (swelling), Urticarial erythema (redness), Allergic pruritus)[5]

[1] (≤ 4 cm).
[2] Transient.
[3] Resolves spontaneously within 1 to 2 weeks.
[4] Slight diffuse.
[5] 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

After reconstitution of the lyophilisate with the solvent, shake gently and administer immediately one dose of 1 ml subcutaneously according to the following vaccination schedule:

Primary vaccination course :
- first injection from 8 weeks of age
- second injection 3 or 4 weeks later.

Maternally derived antibodies may in some cases influence the immune response to vaccination. In such cases, a third injection is recommended from 15 weeks of age.

Re-vaccinations:
One booster injection of a single dose should be given one year after the primary vaccination course.
Subsequent vaccinations are carried out at intervals of up to three years.
Annual revaccination is required for CPiV and Leptospira components, therefore a single dose of the Virbac vaccine against CPiV and Leptospira can be used annually.

9. Advice on correct administration

The appearance of the reconstituted product is slightly pinkish beige.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Store and transport refrigerated (2°C – 8°C).
Protect from light.
Do not freeze.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

Shelf life after reconstitution according to directions: Use immediately.

12. Special precautions for the 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.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 05653/3023

1 x 1 dose lyophilisate and 1 x 1 mL suspension
10 x 1 dose lyophilisate and 10 x 1 mL suspension
25 x 1 dose lyophilisate and 25 x 1 mL suspension
50 x 1 dose lyophilisate and 50 x 1 mL suspension
100 x 1 dose lyophilisate and 100 x 1 mL suspension

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

December 2023

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 manufacturer responsible for batch release and contact details to report suspected adverse reactions:
Virbac
Premiere Avenue
2065M - L I D
F-06516 Carros Cedex
France

Local representatives 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.

Approved: 19 March 2024