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 for dogs

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. PHARMACEUTICAL FORM

Lyophilisate and suspension for suspension for injection.

4. PACKAGE SIZE

1 vial of lyophilisate and 1 vial of suspension
10 vials of lyophilisate and 10 vials of suspension

5. TARGET SPECIES

Dog.

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:
Use immediately after reconstitution.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

16. MARKETING AUTHORISATION NUMBER(S)

Vm 05653/5054

17. MANUFACTURER'S BATCH NUMBER

Batch :{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 for dogs

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. PHARMACEUTICAL FORM

Lyophilisate and suspension for suspension for injection.

4. PACKAGE SIZE

25 vials of lyophilisate and 25 vials of suspension
50 vials of lyophilisate and 50 vials of suspension
100 vials of lyophilisate and 100 vials of suspension

5. TARGET SPECIES

Dog.

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:
Use immediately after reconstitution.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

16. MARKETING AUTHORISATION NUMBER(S)

Vm 05653/5054

17. MANUFACTURER'S BATCH NUMBER

Batch: {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial with lyophilisate

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CANIXIN DHPPi/L

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

DHPPi

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 dose

4. ROUTE(S) OF ADMINISTRATION

SC

5. WITHDRAWAL PERIODS

6. BATCH NUMBER

Batch: {number}

7. EXPIRY DATE

EXP:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial with suspension

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CANIXIN DHPPi/L suspension for dogs

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

L

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 ml

4. ROUTE(S) OF ADMINISTRATION

SC

5. WITHDRAWAL PERIODS

6. BATCH NUMBER

Batch: {number}

7. EXPIRY DATE

EXP:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

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

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

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

4. INDICATION(S)

For active immunisation of dogs from 8 weeks of age to:
- prevent mortality and clinical signs caused by canine distemper virus;
- prevent mortality and clinical signs caused by canine adenovirus type 1;
- prevent clinical signs and mortality and reduce excretion caused by canine parvovirus in challenge studies performed with a CPV-2b strain;
- prevent clinical signs and reduce excretion caused by canine parvovirus in a challenge study performed with a CPV-2c strain;
- reduce respiratory clinical signs and viral excretion caused by canine parainfluenza virus and canine adenovirus type 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. ADVERSE REACTIONS

A transient swelling (≤ 4 cm) or slight diffuse local oedema in rare cases associated with pain or pruritus was commonly observed in safety studies. Any such local reaction resolves spontaneously within 1 to 2 weeks.

Some transient post-vaccinal lethargic states were commonly observed in clinical studies.
Transient hyperthermia or digestive disturbances such as anorexia, diarrhoea or vomiting were rarely observed from spontaneous reports.

Hypersensitivity reactions (e.g. anaphylaxis, skin manifestations such as oedema/swelling, erythema, pruritus) have been reported in very rare cases from spontaneous reports. In case of such an allergic or anaphylactic reaction, appropriate symptomatic treatment should be administered.

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)

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 inform your veterinary surgeon.

Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Dog.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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 Canine Parainfluenza virus and Leptospira can be used annually.

9. ADVICE ON CORRECT ADMINISTRATION

The appearance of the reconstituted product is slightly pinkish beige.

10. WITHDRAWAL PERIODS

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 after the expiry date which is stated on the label after EXP.
Use immediately after reconstitution.

12. SPECIAL WARNING(S)

Special warnings for each target species:
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, route(s) and method of administration”).

Special precautions for use in animals:
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 decided on a case by case basis.

Overdose (symptoms, emergency procedures, antidotes):
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 reactions’ except that the duration of local reactions was increased (up to 26 days).

Incompatibilities:
Do not mix with any other veterinary medicinal product.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

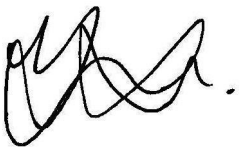
14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

December 2020

15. OTHER INFORMATION

Colourless type I glass vial containing 1 dose of lyophilisate and colourless type I glass vial containing 1 ml of suspension, both closed by a butyl-elastomer stopper and sealed with an aluminium cap, in a plastic or cardboard box.

Pack sizes:
1 vial of lyophilisate and 1 vial of suspension
10 vials of lyophilisate and 10 vials of suspension
25 vials of lyophilisate and 25 vials of suspension
50 vials of lyophilisate and 50 vials of suspension
100 vials of lyophilisate and 100 vials of suspension
Not all pack sizes may be marketed.



Approved: 19 March 2024