LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box containing 1, 5, 10, 25, 50 or 100 vials of lyophilisate and 1, 5, 10, 25, 50 or 100 vials of solvent

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CANIXIN DHPPi lyophilisate and solvent for suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Once reconstituted, each dose of 1 ml contains:

Active substances:

Lyophilisate

Canine distemper virus (CDV), strain Lederle, live attenuated	$10^{3.0}$ - $10^{4.9}$ $CCID_{50}$*
Canine adenovirus type 2 (CAV-2), strain Manhattan, live attenuated	$10^{4.0}$ - $10^{6.0}$ $CCID_{50}$*
Canine parvovirus (CPV), strain Cornell 780916, live attenuated	$10^{5.0}$ - $10^{6.8}$ $CCID_{50}$*
Canine parainfluenza virus (CPiV), strain Manhattan, live attenuated	$10^{5.0}$- $10^{6.9}$ $CCID_{50}$*

* Cell culture infectious dose 50%

3. PACKAGE SIZE

1 x 1 dose lyophilisate and 1 x 1 ml solvent
5 x 1 dose lyophilisate and 5 x 1 ml solvent
10 x 1 dose lyophilisate and 10 x 1 ml solvent
25 x 1 dose lyophilisate and 25 x 1 ml solvent
50 x 1 dose lyophilisate and 50 x 1 ml solvent
100 x 1 dose lyophilisate and 100 x 1 ml solvent

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 NUMBER

Vm 05653/3067

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

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 solvent

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CANIXIN DHPPi solvent

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

1 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

CANIXIN DHPPi lyophilisate and solvent for suspension for injection for dogs

2. Composition

Once reconstituted, each dose of 1 ml contains:

Active substances:

Lyophilisate

Canine distemper virus (CDV), strain Lederle, live attenuated	$10^{3.0}$ - $10^{4.9}$ $CCID_{50}$*
Canine adenovirus type 2 (CAV-2), strain Manhattan, live attenuated	$10^{4.0}$ - $10^{6.0}$ $CCID_{50}$*
Canine parvovirus (CPV), strain Cornell 780916, live attenuated	$10^{5.0}$ - $10^{6.8}$ $CCID_{50}$*
Canine parainfluenza virus (CPiV), strain Manhattan, live attenuated	$10^{5.0}$- $10^{6.9}$ $CCID_{50}$*

* Cell culture infectious dose 50%

Lyophilisate: White lyophilisate.
Solvent: Colourless liquid.

3. Target species

Dogs.

4. Indications for use

For active immunisation of dogs 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;

Onset of immunity:
- From 3 weeks after the primary vaccination for CDV, CAV-2 and CPV
- From 4 weeks after the primary vaccination for CPiV and CAV-1

Duration of immunity:
After the primary vaccination course: one year.
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 or CAV-2.
After the annual booster, the duration of immunity lasts for 3 years for CDV, CAV-1, CAV-2 and CPV and 1 year for CPiV.
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.
In susceptible puppies suspected to present low levels of maternal derived antibodies (i.e. born from non-vaccinated mothers, from large litters, poor feeders,...), an earlier immunisation may be recommended by the veterinarian (i.e. in case of early puppy socialisation, high risk environment,...) and the vaccination scheme should be adapted accordingly (see section “Dosage for each species, routes and method of administration”).
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 each 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:
Safety and efficacy data are available which demonstrate that this vaccine can be mixed and administered with Virbac’s Leptospira vaccine containing the strains *Leptospira interrogans* (serogroup Canicola serovar Canicola and serogroup Icterohaemorrhagiae serovar Icterohaemorrhagiae) or Virbac’s rabies vaccine, if available.
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.

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). In puppies of 6 weeks of age, swelling (≤2cm) sometimes associated with pain and sometimes followed by nodules (≤0.1cm), self-resolving within 2 weeks; may be very commonly observed.

Major incompatibilities:
Do not mix with any other veterinary medicinal product, except solvent supplied for use with the veterinary medicinal product and except those mentioned in section 'Interaction with other medicinal products and other forms of interaction' above.

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 (itching))[5]

[1] (≤ 4 cm). In puppies of 6 weeks of age, swelling (≤ 2cm) sometimes associated with pain and sometimes followed by nodules (≤ 0.1cm), self-resolving within 2 weeks; may be very commonly observed (refer to overdose section).
[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 its local representative using the contact details at the end of this leaflet, or via your national reporting system at https://www.gov.uk/report-veterinary-medicine-problem.

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.

When an early vaccination is recommended in susceptible puppies (see section 'Special warnings'), an additional injection from 6 weeks of age can be performed; followed 2 weeks later (from 8 weeks of age) by the usual vaccination scheme (2 injections performed at a 3-4 weeks interval).

Re-vaccinations:
One booster injection of a single dose should be given 1 year after the primary vaccination course.
Subsequent vaccinations are carried out at intervals of up to three years.
Annual revaccination is required for the CPiV component.

When active immunisation against *Leptospira* is also required, Virbac's Leptospira vaccine can be used instead of the solvent. After reconstitution of one dose of the product with one dose of Virbac's Leptospira vaccine, shake gently (the reconstituted product is slightly pinkish beige) and administer immediately one dose of 1 ml subcutaneously according to the same vaccination schedule as above (annual revaccination required for the *Leptospira* component). Refer to the Virbac's Leptospira's vaccine product information regarding vaccination scheme against *Leptospira*.

When active immunisation against rabies is also required, and if Virbac's rabies vaccine is available, 1 dose of Virbac's rabies vaccine can be used instead of the solvent. Refer to the Virbac's rabies vaccine product information regarding vaccination scheme against rabies.

9. Advice on correct administration

The appearance of the reconstituted product is slightly pink.

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 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 number and pack sizes

Vm 05653/3067

1 x 1 dose lyophilisate and 1 x 1 ml solvent
5 x 1 dose lyophilisate and 5 x 1 ml solvent
10 x 1 dose lyophilisate and 10 x 1 ml solvent
25 x 1 dose lyophilisate and 25 x 1 ml solvent
50 x 1 dose lyophilisate and 50 x 1 ml solvent
100 x 1 dose lyophilisate and 100 x 1 ml solvent

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:
VIRBAC
1ère avenue – 2065m - LID
06516 Carros
France

Local representative and contact details to report suspected adverse events:

Virbac Ireland
McInerney & Saunders
38 Main Street
Swords, Co Dublin
K67 E0A2
Ireland
Tel: +44 (0)-1359 243243

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

17. Other information

POM-V Veterinary medicinal product subject to prescription

In susceptible puppies at 6 weeks of age, safety of the vaccination has been established and benefit of the addition of one injection has been demonstrated based on the following points:
- for CPiv based on the reduction of excretion from 2 weeks after the first 2 injections
- for CDV, CAV-2, CAV-1, CPV2 and CPV2-c based on the presence of antibodies 2 weeks after one single injection.

Approved 10 November 2026
Gavin Hall