LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard or plastic box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Canigen DHP lyophilisate and solvent for suspension for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 1 ml dose of reconstituted vaccine contains:

Canine distemper virus, strain Onderstepoort ≥ $10^{4.0}$ $TCID_{50}$

Canine adenovirus 2, strain Manhattan LPV3 ≥ $10^{4.0}$ $TCID_{50}$

Canine parvovirus, strain 154 ≥ $10^{7.0}$ $TCID_{50}$.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

4. PACKAGE SIZE

50 x 1 dose

10 x 1 dose

5. TARGET SPECIES

Dogs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use.

Read package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP: {month/year}

Once reconstituted use within 30 minutes.

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.

Do not freeze.

Protect from light.

Keep vials in the outer box.

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

Disposal: read package leaflet.

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

For animal treatment only.

POM-V

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

MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
MK7 7AJ

Distributor:

Virbac Ltd.
Woolpit Business Park
Windmill Avenue
Woolpit
Bury St. Edmunds
Suffolk, IP30 9UP

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4620

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1 dose vial label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Canigen DHP

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

CDV ≥ $10^{4.0}$ $TCID_{50}$

CAV 2≥ $10^{4.0}$ $TCID_{50}$

CPV ≥ $10^{7.0}$ $TCID_{50}$

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

1 dose

4. ROUTE(S) OF ADMINISTRATION

SC

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Lot: {number}

7. EXPIRY DATE

EXP: {month/year}

Once reconstituted use within 30 minutes.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

Additional text

POM-V

Vm 01708/4620

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Canigen DHP lyophilisate and solvent for suspension for injection

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

Marketing authorisation holder:

MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturer for the batch release:

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Canigen DHP lyophilisate and solvent for suspension for injection

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

Each 1 ml dose of reconstituted vaccine contains:

Active substances:

Canine distemper virus, strain Onderstepoort	$\geq 10^{4.0}$ $TCID_{50*}$
Canine adenovirus 2, strain Manhattan LPV3	$\geq 10^{4.0}$ $TCID_{50*}$
Canine parvovirus, strain 154	$\geq 10^{7.0}$ $TCID_{50*}$

*Tissue culture infective dose 50%

Solvent (1 ml per vial):

Phosphate buffered saline

4. INDICATION(S)

For the active immunisation of dogs to:

- reduce clinical signs of disease caused by canine distemper virus infection;
- prevent clinical signs and viral excretion caused by canine parvovirus infection
- reduce clinical signs of canine contagious hepatitis and viral excretion due to canine adenovirus 1 infection, and
- reduce clinical signs of respiratory infection and viral excretion caused by adenovirus type 2 infection.

Onset of immunity: 1 week.

Duration of immunity: 3 years.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

A common reaction after subcutaneous administration with the diluent provided, is a diffuse swelling up to 5 mm in diameter at the site of injection. Occasionally this swelling may be hard and painful and last for up to 3 days post injection.

In rare cases a transient rise in body temperature and/or a transient acute hypersensitivity reaction (anaphylaxis) - with signs that may include lethargy, facial oedema, pruritus, dyspnoea, vomiting, diarrhoea or collapse - may occur shortly after vaccination.

Clinical signs of immune-mediated haemolytic anaemia, immune-mediated

thrombocytopenia or immune-mediated polyarthritis have been reported in very rare cases

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

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)

7. TARGET SPECIES

Dogs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Subcutaneous use.

The contents of one vial of reconstituted vaccine should be injected subcutaneously. Reconstitute immediately prior to use by the addition of the contents of one vial (1 ml) of Canigen Lepto 2, Canigen L4 (canine leptospirosis vaccines), Canigen Rabies, or Canigen Solvent.

Vaccination regime

Primary course vaccination:
A single injection should establish active immunity in dogs of 10 weeks of age or older. Where earlier protection is required a first dose may be given to puppies from 6 weeks of age, but because maternally derived passive antibody can interfere with the response to vaccination a final dose should be given 2 - 4 weeks later i.e. at 10 weeks of age or older.
Booster vaccination:
To maintain protection a single booster dose is recommended every three years.

9. ADVICE ON CORRECT ADMINISTRATION

Sterile equipment should be used for administration.
Avoid contamination of vaccine with traces of chemical sterilising agents. Do not use chemicals such as disinfectant or spirit to disinfect the skin prior to inoculation.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store in a refrigerator (2 °C – 8 °C).
Do not freeze.
Protect from light.

Keep the vials in the outer box.

Reconstituted vaccine: Store in a refrigerator at 2 ° C – 8 °C with care being taken to avoid prolonged or repetitive exposure to high ambient temperature following withdrawal from the refrigerator prior to use.

Shelf life after reconstitution: 30 minutes.

Do not use after the expiry date stated on the label and outer packaging.

12. SPECIAL WARNING(S)

Special warnings for each target species:

The efficacy of the CDV, CAV2 and CPV components of the vaccine may be reduced due to maternal antibody interference. However, the vaccine has been proved to be of benefit against virulent challenge in the presence of maternal antibody levels to CDV, CAV2 and CPV that are likely to be encountered under field conditions.

Special precautions for use in animals:

Only healthy dogs should be vaccinated. Dogs should not be exposed to unnecessary risk of infection within the first 2 weeks after completion of the vaccination regimen.

While the canine parvovirus vaccine strain may be shed at very low levels for up to 8 days after inoculation, there is no evidence that this results in clinical symptoms if non-vaccinated animals are infected.

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

In the case of accidental self-injection, wash the area immediately with water. If symptoms develop, seek medical attention showing a copy of package leaflet.

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 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.

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 DHP and an overdose of the leptospirosis vaccines of 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 of the Canigen range against rabies. After administration with the rabies vaccine, where this product is authorised, 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 and efficacy data are available which demonstrate that this vaccine can be administered on the same day, but not mixed, with the live vaccine for intranasal administration of the Canigen range against infectious tracheobronchitis caused by *Bordetella bronchiseptica* and/or canine parainfluenza virus.

Safety and efficacy data are available which demonstrate that this vaccine can be administered at the same time but not mixed with the inactivated vaccine of the Canigen range against *Bordetella bronchiseptica*.

When Canigen DHP 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.

Consult product leaflets before administering products simultaneously.

Pregnancy and lactation:

Can be used in pregnant bitches which have previously been vaccinated with the CDV (strain Onderstepoort), CAV2 (strain Manhattan LPV3) and CPV (strain 154) antigens included in the Canigen vaccine range.

Overdose (symptoms, emergency procedures, antidotes):

After administration of an overdose no effects other than those listed in section 6.

Incompatibilities:

Do not mix with any other veterinary medicinal products except the solvent or the vaccines in the Canigen range listed above.

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 products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2022

15. OTHER INFORMATION

For animal treatment only.

ATCvet code: QI07AD02

The vaccine contains attenuated antigens to stimulate active immunity in dogs against canine distemper virus, canine parvovirus, canine contagious hepatitis caused by canine adenovirus 1 and respiratory disease caused by canine adenovirus type 2.

Pack sizes:

Cardboard or plastic boxes containing 10 or 50 single dose vials.
The solvent may be packed with the vaccine or separately.
Not all pack sizes may be marketed.

Legal category

POM-V

To be supplied only on veterinary prescription

MA number: Vm 01708/4620

Distributor:

Virbac Ltd.
Woolpit Business Park
Windmill Avenue
Woolpit
Bury St. Edmunds
Suffolk, IP30 9UP

Approved 25 October 2022