PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box of 10 doses: 10 vials (glass) of 1 dose of lyophilisate Box of 50 doses: 50 vials (glass) of 1 dose of lyophilisate

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eurican DHPPi lyophilisate for suspension for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 dose contains
Attenuated distemper virus ..... $10^{4.0-6.0}$ CCID50
Attenuated canine adenovirus type 2 ..... $10^{2.5-6.3}$ CCID50
Attenuated canine parvovirus type 2 ..... $10^{4.9-7.1}$ CCID50
Attenuated canine parainfluenza type 2 virus ..... $10^{4.7-7.1}$ CCID50

3. PHARMACEUTICAL FORM

Lyophilisate for suspension for injection.

4. PACKAGE SIZE

10 doses : 10x1 dose lyophilisate.
50 doses : 50x1 dose lyophilisate.

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Use immediately after reconstitution.

11. SPECIAL STORAGE CONDITIONS

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

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

Disposal: Read the package leaflet before use.

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.

POM-V (UK)

POM (Ireland)

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

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

Boehringer Ingelheim Vetmedica GmbH, 55216 Ingelheim/Rhein, Germany

16. MARKETING AUTHORISATION NUMBER

UK: Vm 08327/4126 IE: VPA10454/040/001

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Lyophilisate: 1 dose

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eurican DHPPi

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

DHPPi

Read package leaflet before use.

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

1 dose

4. ROUTE(S) OF ADMINISTRATION

SC

5. WITHDRAWAL PERIOD

Not applicable

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

PACKAGE LEAFLET FOR:

Eurican DHPPi lyophilisate 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:
Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

Boehringer Ingelheim Vetmedica GmbH, 55216 Ingelheim/Rhein, Germany

Manufacturer responsible for batch release:
Boehringer Ingelheim Animal Health France SCS
Laboratoire Portes des Alpes
Rue de l'Aviation
69800 Saint Priest
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eurican DHPPi lyophilisate for suspension for injection

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

One dose of lyophilisate contains:

Attenuated Canine Distemper virus,

	Minimum	**Maximum**
strain BA5	$10^{4.0}$ CCID50*	$10^{6.0}$ CCID50*
Attenuated Canine Adenovirus type 2, strain DK13	$10^{2.5}$ CCID50*	$10^{6.3}$ CCID50*
Attenuated Canine Parvovirus type 2, strain CAG2	$10^{4.9}$ CCID50*	$10^{7.1}$ CCID50*
Attenuated Canine Parainfluenza virus type 2, Strain CGF 2004/75	$10^{4.7}$ CCID50*	$10^{7.1}$ CCID50*

(* CCID50: 50% cell culture infective dose)

4. INDICATION(S)

Active immunisation of dogs to:

- prevent mortality and clinical signs caused by canine distemper virus (CDV),
- prevent mortality and clinical signs caused by infectious canine hepatitis virus (CAV),
- reduce viral excretion during respiratory disease caused by canine adenovirus

type 2 (CAV-2),
- prevent mortality, clinical signs and viral excretion caused by canine parvovirus (CPV)*,
- reduce viral excretion caused by canine parainfluenza virus type 2 (CPiV),

Onset of immunity : 2 weeks for all strains

Duration of immunity: at least one year after the second injection of the primary vaccination course for all strains.

Current available challenge and serological data show that protection for distemper virus, adenovirus and parvovirus* lasts for 2 years after primary vaccination course followed by a first annual booster.
Any decision to adapt the vaccination schedule of this veterinary medicinal product needs to be made on a case by case basis, taking into account the vaccination history of the dog and the epidemiological context.
*Protection has been demonstrated against canine parvovirus type 2a, 2b and 2c either by challenge (type 2b) or serology (type 2a and 2c).

5. CONTRAINDICATIONS

None

6. ADVERSE REACTIONS

Immediately after injection, a slight swelling (≤ 2 cm) may commonly be observed at the injection site, usually regressing within 1-6 days. This can, on some occasions, be accompanied by slight pruritus, heat and pain at the injection site. Transient lethargy and emesis may also be commonly observed.

Uncommon reactions such as anorexia, polydipsia, hyperthermia, diarrhoea, muscle tremor, muscle weakness and injection site cutaneous lesions may be observed.

As with any vaccine, rare hypersensitivity reactions may occur. In such cases, appropriate symptomatic treatment should be provided.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

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

7. TARGET SPECIES

Dogs

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

After reconstitution, inject a 1-ml dose subcutaneously according to the following schedule:

Primary vaccination: Two injections separated by an interval of 4 weeks from 7 weeks of age.
When administered with Boehringer Ingelheim's vaccines containing rabies, the minimum age for vaccination is 12 weeks of age.

In cases where high levels of maternally derived antibodies are suspected by the veterinarian and the primary vaccination course was completed before 16 weeks of age, a third injection using a Boehringer Ingelheim vaccine containing Distemper, Adenovirus and Parvovirus is recommended from 16 weeks of age, at least 3 weeks after the second injection.

Revaccination: Administer one dose 12 months after completion of the primary vaccination course. Dogs should be revaccinated with a single booster dose on an annual basis.

9. ADVICE ON CORRECT ADMINISTRATION

Aseptically reconstitute the contents of the lyophilisate with a compatible Boehringer Ingelheim vaccine (Eurican LR, Eurican L or Eurican Lmulti) where available. Shake well before use. The entire contents of the reconstituted vial should be administered as a single dose. The reconstituted contents shall be an opalescent yellow to orange suspension.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store and transport refrigerated (2°C-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 after “EXP”.
Shelf-life after reconstitution according to directions: use immediately.

12. SPECIAL WARNING(S)

Special precautions for use in animals:
Vaccinate healthy animals only.
Apply usual aseptic procedures.
After vaccination, the live CAV-2 and CPV vaccine strains can transiently be shed without adverse consequence for 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: Can be used during pregnancy.

Interaction with other medicinal products and other forms of interaction:
Safety and efficacy data are available which demonstrate that this vaccine can be administered with Eurican LR, Eurican L or Eurican Lmulti vaccines (used as diluent) where available.
Safety and efficacy data are available which demonstrate that this vaccine can be administered on the same day but not mixed with Rabisin vaccine if the vaccine has been reconstituted with Eurican L or Eurican Lmulti.
When administered with Boehringer Ingelheim's vaccines containing rabies, the minimum age for vaccination is 12 weeks of age.
When administered reconstituted with the Eurican LR vaccine a small and transient nodule (maximum size 1.5 cm) at the injection site may be induced due to the presence of aluminium hydroxide and a slight swelling (~4 cm) may occur after the injection at injection site, regressing generally within 1-4 days. 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:
No adverse reactions other than those mentioned in section ‘adverse reactions” were observed after administration of a 10-fold overdose of the lyophilisate.

Incompatibilities:
Do not mix with any other veterinary medicinal product except the compatible vaccines (Eurican LR, Eurican L or Eurican Lmulti).

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

April 2020

15. OTHER INFORMATION

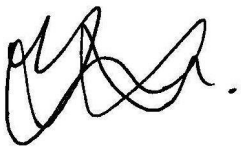
Plastic box of 10 vials (glass) of lyophilisate (1 dose)
Plastic box of 50 vials (glass) of lyophilisate (1 dose)

Not all pack sizes may be marketed.

POM-V Vm 08327/4126

VPA 10454/040/001

POM Prescription Only Medicine



Approved: 27 May 2020