

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eurican DHPPi lyophilisate for suspension for injection.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substances:

	Minimum	Maximum
Attenuated canine distemper virus, strain BA5	10 ^{4.0} CCID ₅₀ *	10 ^{6.0} CCID ₅₀ *
Attenuated canine adenovirus type 2, strain DK13	10 ^{2.5} CCID ₅₀ *	10 ^{6.3} CCID ₅₀ *
Attenuated canine parvovirus type 2, strain CAG2	10 ^{4.9} CCID ₅₀ *	10 ^{7.1} CCID ₅₀ *
Attenuated canine parainfluenza virus type 2, strain CGF 2004/75	10 ^{4.7} CCID ₅₀ *	10 ^{7.1} CCID ₅₀ *

(* CCID₅₀: 50% cell culture infective dose)

Excipients:

Qualitative composition of excipients and other constituents
<i>Lyophilisate:</i>
<i>Casein hydrolysate</i>
<i>Gelatin</i>
<i>Dextran 40</i>
<i>Dipotassium phosphaaate</i>
<i>Potassium dihydrogen phosphate</i>
<i>Potassium hydroxide</i>
<i>Sorbitol</i>
<i>Sucrose</i>
<i>Water for injections</i>

3. CLINICAL INFORMATION

3.1 Target species

Dogs

3.2 Indications for use for each target species

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-1),
- 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 after the second injection of the primary vaccination course 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).

3.3 Contraindications

None.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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.

Special precautions for the protection of the environment:

Not applicable.

Other precautions:

3.6 Adverse events

Dogs:

Common (1 to 10 animals / 100 animals treated):	Injection site swelling ¹ , injection site pruritus, injection site pain. Lethargy ² . Emesis ² .
Uncommon (1 to 10 animals / 1,000 animals treated):	Anorexia, polydipsia, hyperthermia. Diarrhoea. Muscle tremor. Muscle weakness. Injection site warmth, injection site lesions ³ .
Rare (1 to 10 animals / 10,000 animals treated):	Hypersensitivity reaction (facial oedema, anaphylactic shock, urticaria) ⁴ .

¹ Slight (≤ 2 cm), immediately after injection. It usually regresses within 1-6 days.

² Transient.

³ Cutaneous.

⁴ Some of which are life-threatening. Appropriate symptomatic treatment should promptly be provided.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Can be used during pregnancy.

3.8 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, Eurican Lmulti or Eurican L4 vaccines (used as solvent) 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 if the vaccine has been reconstituted with Eurican L, Eurican Lmulti or Eurican L4.

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.

When mixed with the Eurican L4 vaccine a swelling (less than 6 cm) may very commonly occur at the injection site, disappearing within 8 days, anorexia may commonly occur and vocalisation, tachycardia and tachypnoea may uncommonly be observed. For Eurican L4, no safety data in pregnant bitches are available for the additional inactivated strain, *Leptospira Australis*.

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.

3.9 Administration routes and dosage

Aseptically reconstitute the contents of the lyophilizate with a compatible Boehringer Ingelheim vaccine (Eurican LR, Eurican L, Eurican Lmulti or Eurican L4) 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.

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No adverse events other than those mentioned in section 3.6 were observed after administration of a 10-fold overdose of the lyophilizate.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI07AD04

Vaccine against canine distemper virus, canine adenovirus (CAV-1 and CAV- 2), canine parvovirus and parainfluenza type 2 infections.

After administration, the vaccine induces an immune response in dogs against infections caused by distemper, adenoviroses (CAV-1 and CAV-2), parvovirus and parainfluenza type 2 demonstrated by challenge and by the presence of antibodies.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medical product except the compatible vaccines (Eurican LR, Eurican L, Eurican Lmulti or Eurican L4) mentioned in section 3.8.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after reconstitution according to directions: use immediately.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Type I glass vials with chlorobutyl stoppers, sealed with aluminium caps.

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.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Limited
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS
United Kingdom

7. MARKETING AUTHORISATION NUMBER(S)

Vm 08327/4126

8. DATE OF FIRST AUTHORISATION

19 June 1997.

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

December 2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

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