SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eurican DHPPi lyophilisate for suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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)

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Beige to pale yellow lyophilisate for suspension for injection.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs.

4.2 Indications for use, specifying the 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),
- 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).

4.3 Contraindications

None.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

i) 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.

ii) Special precautions for 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.

4.6 Adverse reactions (frequency and seriousness)

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).

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy.

4.8 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 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 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.

4.9 Amount(s) to be administered and administration route

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.

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No adverse reactions other than those mentioned in section 4.6 were observed after administration of a 10-fold overdose of the lyophilisate.

4.11 Withdrawal period(s)

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

ATCvet code: QI07AD04
Pharmacotherapeutic group: -Live viral vaccines

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), parvovirosis and parainfluenza type 2 demonstrated by challenge and by the presence of antibodies.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Casein hydrolysate
Gelatin
Dextran 40
Dipotassium phosphate
Potassium dihydrogen phosphate
Potassium hydroxide

Sorbitol
Sucrose
Water for injections

6.2 Incompatibilities

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

6.3 Shelf life

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

6.4 Special precautions for storage

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

6.5 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.

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

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

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 08327/4126

9. DATE OF FIRST AUTHORISATION

19 June 1997

10. DATE OF REVISION OF THE TEXT

27 May 2020

Approved 27 May 2020