1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eurican DAP lyophilisate and solvent for suspension for injection.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml dose of vaccine contains:
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	$10^{4.9}$ $CCID_{50}$*	$10^{7.1}$ $CCID_{50}$*

* $CCID_{50}$: 50 % cell culture infective dose

Excipients:

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

Beige to pale yellow lyophilisate and colourless liquid.

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)*.

Onset of immunity: 2 weeks after the second injection of the primary vaccination course.

Duration of immunity: at least one year after the second injection of the primary vaccination course and at least 2 years after the first annual booster.
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

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:
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.

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 its local representative 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 vaccine.
When administered with Boehringer Ingelheim's vaccines containing rabies, the minimum age for vaccination is 12 weeks of age.
When mixed 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 lyophilisate with either solvent for Eurican DAP/DAPPi or 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 content 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 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 every two years after the first annual booster

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

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

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: QI07AD02

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

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

5. PHARMACEUTICAL PARTICULARS

5.1 Major Incompatibilities

Do not mix with any other veterinary medicinal product except the solvent for Eurican DAP/DAPPi, supplied for use with the veterinary medicinal product, and except those mentioned in section 3.8 above.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf-life of the solvent as packaged for sale: 3 years.
Shelf-life after reconstitution according to directions: use immediately.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Immediate container: type I glass vials with chlorobutyl rubber stoppers, sealed with aluminium caps.

Outer container:
Plastic box of 10 vials of lyophilisate (1 dose) and 10 vials of solvent (1 ml).
Plastic box of 50 vials of lyophilisate (1 dose) and 50 vials of solvent (1 ml).

Plastic box of 10 vials of lyophilisate (1 dose).

Plastic box of 50 vials of lyophilisate (1 dose).

Plastic box of 10 vials of solvent (1 ml).
Plastic box of 50 vials of solvent (1 ml).

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 Vetmedica GmbH

7. MARKETING AUTHORISATION NUMBER(S)

VPA10454/038/001

8. DATE OF FIRST AUTHORISATION

15 July 2016

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

01 February 2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).