

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Eurican DAP lyophilisate and solvent for suspension for injection

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

One dose of vaccine (1 ml) contains:

Lyophilisate:

#### **Active substances:**

	<b>Minimum</b>	<b>Maximum</b>
Attenuated canine distemper virus, strain BA5	10 <sup>4.0</sup> CCID <sub>50</sub> *	10 <sup>6.0</sup> CCID <sub>50</sub> *
Attenuated canine adenovirus type 2, strain DK13	10 <sup>2.5</sup> CCID <sub>50</sub> *	10 <sup>6.3</sup> CCID <sub>50</sub> *
Attenuated canine parvovirus type 2, strain CAG2	10 <sup>4.9</sup> CCID <sub>50</sub> *	10 <sup>7.1</sup> CCID <sub>50</sub> *

\* CCID<sub>50</sub>: 50% cell culture infective dose

#### **Solvent:**

Sterilised water for injections 1 ml.

#### **Excipients:**

For the full list of excipients, see section 6.1.

### **3. PHARMACEUTICAL FORM**

Lyophilisate and solvent for suspension for injection.  
Beige to pale yellow lyophilisate and colourless liquid.

### **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-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 for all strains.

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 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**

Vaccinate healthy animals only.

#### **4.5 Special precautions for use**

##### Special precautions for use in animals

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.

#### **4.6 Adverse reactions (frequency and seriousness)**

A slight swelling ( $\leq 2$  cm) at the injection site may commonly be observed immediately after injection. It usually regresses 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.

Anorexia, polydipsia, hyperthermia, diarrhoea, muscle tremor, muscle weakness and injection site cutaneous lesions may uncommonly be observed.

Hypersensitivity reactions (facial oedema, anaphylactic shock, urticaria) may rarely occur, some of which are life-threatening. Appropriate symptomatic treatment should promptly be provided.

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).

#### 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 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.

#### 4.9 Amounts to be administered and administration route

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

#### **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: QI07AD02.

Pharmacotherapeutic group: Immunologicals for Canidae, live viral vaccines for dogs.

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

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

### **6. PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

##### **Lyophilisate**

Casein hydrolysate

Gelatin

Dextran 40

Dipotassium phosphate

Potassium dihydrogen phosphate

Potassium hydroxide

Sorbitol

Sucrose

Water for injections

##### **Solvent**

Water for injections

#### **6.2 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 4.8 above.

#### **6.3 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.

#### **6.4 Special precautions for storage**

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

#### **6.5 Nature and composition of immediate packaging**

Immediate container: type I (lyophilisate) or type II (solvent) 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.

#### **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

### **8. MARKETING AUTHORISATION NUMBER**

Vm 08327/5023

### **9. DATE OF FIRST AUTHORISATION**

26 May 2016

**10. DATE OF REVISION OF THE TEXT**

June 2024

*Gavin Hall*

Approved 12 June 2024