SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eurican DAPPi lyophilisate and solvent for suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose of vaccine (1 ml) contains:

Lyophilisate:
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	$10^{4.7}$ $CCID_{50}$*	$10^{7.1}$ $CCID_{50}$*

(* $CCID_{50}$: 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),
- 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).

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 (≤ 2 cm) may commonly be observed at the injection site 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 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.
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.
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 sterile diluent or 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 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 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: Immunologicals for Canidae, live viral vaccines for dogs.

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 distemper, adenoviroses (CAV-1 and CAV-2), parvovirosis and parainfluenza type 2 respiratory infections 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 supplied for use with the veterinary medicinal product or 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

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 100 vials of lyophilisate (1 dose) and 100 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 08327/4277

9. DATE OF FIRST AUTHORISATION

26 May 2016

10. DATE OF REVISION OF THE TEXT

February 2021

Approved 04 February 2021