ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box of 10 doses: 10 vials (glass) of 1 dose of lyophilisate and 10 vials (glass) of 1 ml of solvent
Box of 50 doses: 50 vials (glass) of 1 dose of lyophilisate and 50 vials (glass) of 1 ml of solvent

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eurican DAP
lyophilisate and solvent for suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Per dose:
Attenuated distemper virus .....$10^{4.0-6.0}$ $CCID_{50}$
Attenuated canine adenovirus type 2 .....$10^{2.5-6.3}$ $CCID_{50}$
Attenuated canine parvovirus type 2 .....$10^{4.9-7.1}$ $CCID_{50}$.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

4. PACKAGE SIZE

10 doses: 10 x 1 dose lyophilisate + 10 x 1 ml solvent.
50 doses: 50 x 1 dose lyophilisate + 50 x 1 ml solvent.

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once reconstituted: use immediately.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08327/4276

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Lyophilisate vials: 1 dose

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eurican DAP

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

DAP
Read package leaflet before use.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 dose

4. ROUTE(S) OF ADMINISTRATION

SC

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Solvent vials: 1 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eurican DAP
Solvent

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Read package leaflet before use.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 ml

4. ROUTE(S) OF ADMINISTRATION

SC

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Eurican DAP lyophilisate and solvent for suspension for injection

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Boehringer Ingelheim Animal Health UK Limited
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS

Manufacturer responsible for batch release:
Boehringer Ingelheim Animal Health France SCS, Laboratoire Porte des Alpes
Rue de l'Aviation
69800 Saint-Priest
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eurican DAP lyophilisate and solvent for suspension for injection

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

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	$10^{4.9}$ $CCID_{50}$*	$10^{7.1}$ $CCID_{50}$*

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

Solvent:
Sterilised water for injections 1 ml.

Beige to pale yellow lyophilisate and colourless liquid.

4. INDICATIONS

Active immunization 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).

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).

5. CONTRAINDICATIONS

None

6. ADVERSE REACTIONS

A slight swelling (≤ 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).

If you notice any side effects, even those not already listed in this package leaflet or you think that this medicine has not worked, please inform your veterinary surgeon. Alternately you can report via your national reporting system.

7. TARGET SPECIES

Dogs

8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

After reconstitution, 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.

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store and transport refrigerated (2 °C - 8 °C).
Do not freeze.
Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after “EXP”.

Shelf-life after reconstitution according to directions: use immediately.

12. SPECIAL WARNINGS

Special warnings for each target species:
Vaccinate healthy animals only.

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.

Pregnancy:
Can be used during pregnancy.

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.

Overdose:
No adverse reactions other than those mentioned in section ‘Adverse reactions’ were observed after administration of a 10-fold overdose of the lyophilisate.

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).

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

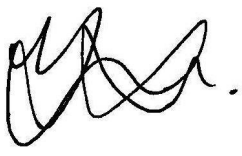
14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

January 2021

15. OTHER INFORMATION

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).

Not all pack sizes may be marketed.



Approved: 02 February 2021