

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Plastic box of 10 doses: 10 vials (glass) of 1 dose of lyophilisate and 10 vials (glass) of 1 ml of solvent for suspension.

Plastic box of 50 doses: 50 vials (glass) of 1 dose of lyophilisate and 50 vials (glass) of 1 ml of solvent for suspension.

Plastic box of 100 doses: 100 vials (glass) of 1 dose of lyophilisate and 100 vials (glass) of 1 ml of solvent for suspension.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eurican DAPPi
lyophilisate and solvent for suspension for injection.

2. STATEMENT OF ACTIVE SUBSTANCES

Per dose (1 ml):

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
Attenuated canine parainfluenza type 2 virus	$10^{4.7-7.1}$	CCID ₅₀

3. 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.

100 doses: 100 x 1 dose lyophilisate + 100 x 1 ml solvent.

4. TARGET SPECIES

Dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {dd/mm/yyyy}
Once reconstituted: use immediately.

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd

14. MARKETING AUTHORISATION NUMBERS

Vm 08327/3022

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Plastic box of 10 vials (glass) of 1 dose of lyophilisate
Plastic box of 50 vials (glass) of 1 dose of lyophilisate
Plastic box of 100 vials (glass) of 1 dose of lyophilisate

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eurican DAPPi
lyophilisate for suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Per dose (1 ml):
Attenuated distemper virus10^{4.0-6.0} CCID₅₀
Attenuated canine adenovirus type 210^{2.5-6.3} CCID₅₀
Attenuated canine parvovirus type 2.....10^{4.9-7.1} CCID₅₀
Attenuated canine parainfluenza type 2 virus10^{4.7-7.1} CCID₅₀

3. PACKAGE SIZE

10 doses: 10 x 1 dose
50 doses: 50 x 1 dose
100 doses: 100 x 1 dose

4. TARGET SPECIES

Dogs

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIOD(S)

8. EXPIRY DATE

Exp. {dd/mm/yyyy}

Once reconstituted: use immediately.

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd

14. MARKETING AUTHORISATION NUMBER(S)

Vm 08327/3022

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box of solvent

Plastic box of 10 vials (glass) of 1 ml of solvent.
Plastic box of 50 vials (glass) of 1 ml of solvent.
Plastic box of 100 vials (glass) of 1 ml of solvent.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Solvent for Eurican DAP/DAPPi

2. STATEMENT OF ACTIVE SUBSTANCES

Water for injections 1 ml

3. PACKAGE SIZE

10 x 1 ml
50 x 1 ml
100 x 1 ml

4. TARGET SPECIES

Dogs

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIOD(S)

8. EXPIRY DATE

Exp. {dd/mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet supplied with the vaccine before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd

14. MARKETING AUTHORISATION NUMBER(S)

Vm 08327/3022

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Lyophilisate vial: 1 dose

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eurican DAPPi



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

DAPPi

1 d.

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {dd/mm/yyyy}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Solvent vial: 1 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

solvent for Eurican DAP/DAPPi



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

1 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {dd/mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Eurican DAPPi lyophilisate and solvent for suspension for injection.

1. Name of the veterinary medicinal product

Eurican DAPPi lyophilisate and solvent for suspension for injection.

2. Composition

Each 1 ml dose contains:
Lyophilisate:

Active substance:

	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 *

* CCID₅₀: 50 % cell culture infective dose

Solvent:

Water for injections 1 ml

Beige to pale yellow lyophilisate and colourless liquid.

3. Target species

Dogs

4. Indications for use

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),
- 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.

Duration of immunity: at least one year after the second injection of the primary vaccination course.

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. Special warnings

Special warnings:

Vaccinate healthy animals only.

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.

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, 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

Overdose:

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

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 subsection “Interaction” above.

7. Adverse events

Dogs:

Common (1 to 10 animals / 100 animals treated):

Injection site swelling¹, injection site pruritus, injection site pain. Lethargy². Emesis².

Uncommon (1 to 10 animals / 1,000 animals treated):

Anorexia, polydipsia, hyperthermia. Diarrhoea. Muscle tremor. Muscle weakness. Injection site warmth, injection site lesions³.

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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system. {national system details}

8. Dosage for each species, routes 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 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.

9. Advice on correct administration

Aseptically reconstitute the contents of the lyophilisate with either solvent for Eurican DAP/DAPPi or a compatible 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.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Lyophilisate and solvent:

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 precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 08327/3022

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).

Plastic box of 10 vials of lyophilisate (1 dose).
Plastic box of 50 vials of lyophilisate (1 dose).
Plastic box of 100 vials of lyophilisate (1 dose).

Plastic box of 10 vials of solvent (1 ml).
Plastic box of 50 vials of solvent (1 ml).
Plastic box of 100 vials of solvent (1 ml).

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

February 2024

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

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse events:

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

Local representatives and contact details to report suspected adverse events:

17. Other information

Gavin Hall

Approved 18 May 2024