# PARTICULARS TO APPEAR ON THE OUTER PACKAGE (CARTON)

# 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eurican P

# 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 1ml dose contains attenuated canine parvovirus  $\geq 10^{4.9}$  CCID<sub>50</sub>.

# 3. PHARMACEUTICAL FORM

Lyophilisate for suspension.

#### 4. PACKAGE SIZE

10 x 1 dose

10 vials each containing a single dose of vaccine

#### 5. TARGET SPECIES

Dogs from 8 weeks of age

# 6. INDICATION(S)

Attenuated canine parvovirus vaccine

# 7. METHOD AND ROUTE(S) OF ADMINISTRATION

for subcutaneous injection

# 8. WITHDRAWAL PERIOD

# 9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

# 10. EXPIRY DATE

# 11. SPECIAL STORAGE CONDITIONS

Store and transport at +2°C - +8°C, protected from light. Do not freeze. Use immediately after reconstitution.

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

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant approved for use by the competent authorities.

# 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.

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

Keep out of the reach and sight of children.

# 15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MERIAL Animal Health Ltd., PO Box 327, Harlow, Essex, CM19 5TG

# 16. MARKETING AUTHORISATION NUMBER(S)

Vm 08327/4151

#### 17. MANUFACTURER'S BATCH NUMBER

# MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS (VIAL LABEL)

1. NAME OF THE VETERINARY ME	EDICINAL PRODUCT
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Eurican P

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Living canine parvovirus vaccine (attenuated canine parvovirus ≥ 10<sup>4,9</sup>CCID<sub>50</sub>).

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

One dose

- 4. ROUTE(S) OF ADMINISTRATION
- s.c. injection
- 5. WITHDRAWAL PERIOD
- **6. BATCH NUMBER**

Batch

7. EXPIRY DATE

Exp.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

9. FURTHER INFORMATION

POM-V

Merial

# PACKAGE LEAFLET FOR: Eurican P

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

Marketing Authorisation holder:

**MERIAL Animal Health Ltd.** 

PO Box 327, Sandringham House Harlow, Essex, CM19 5TG. UK

Manufacturer for the batch release:

**MERIAL Laboratory** 

Porte des Alpes, France

#### 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eurican P

Lyophilisate for suspension.

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

Each 1 ml dose of vaccine contains

Freeze-dried pellet:

Attenuated canine

parvovirus ...... ≥ 10<sup>4.9</sup> CCID<sub>50</sub>

• Excipients qs 1 dose.

# 4. INDICATION(S)

Active immunisation of dogs from 8 weeks of age to prevent clinical signs and to reduce mortality and viral excretion caused by canine parvovirosis infection.

Onset of immunity: 7 days after primary vaccination.

Duration of immunity: 2 years.

# 5. CONTRAINDICATIONS

None.

# 6. ADVERSE REACTIONS

In rare cases, slight and transient pain may be apparent at the time of injection, which regresses within 2 hours.

In exceptional circumstances a hypersensitivity reaction may occur which may require appropriate symptomatic treatment.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary practitioner.

#### 7. TARGET SPECIES

Dogs and puppies from 8 weeks of age.

# 8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Reconstitute EURICAN P using EURICAN L immediately before use. Apply usual aseptic procedures.

Inject by the subcutaneous route.

It is well documented that high levels of maternally derived antibodies can interfere with an active immune response to vaccination. Ideally pups should be vaccinated as soon as maternal antibody has declined to a level at which the pup is susceptible. Under most practical circumstances, this is not known and therefore the following regime is recommended.

For dogs and puppies from 8 weeks of age inject a 1 ml dose according to the following schedule:

Basic Vaccination Scheme:

- Puppies less than 12 weeks old:

1st injection: from 8 weeks of age.

2nd injection: 3 to 5 weeks later, from

12 weeks of age.

- Puppies older than 12 weeks of age:

A single injection is sufficient to confer immunity.

Re-vaccination Scheme:

One injection of EURICAN P every two years.

#### 9. ADVICE ON CORRECT ADMINISTRATION

Can be used during pregnancy. In the absence of data from studies in seronegative bitches, the vaccine should only be used in pregnant bitches which have previously been vaccinated before pregnancy.

# 10. WITHDRAWAL PERIOD(S)

Not applicable.

# 11. SPECIAL STORAGE PRECAUTIONS

Store and transport at  $+ 2^{\circ}\text{C} - + 8^{\circ}\text{C}$ , protected from light. Do not freeze.

Do not used after the expiry date stated on the label.

Use immediately after reconstitution.

Keep out of the reach and sight of children.

# 12. SPECIAL WARNING(S)

Safety and efficacy data are available which demonstrate that this vaccine can be reconstituted in Eurican L. No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the product 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.

The CPV vaccine strain of EURICAN P may be shed from vaccinated animals for a number of days following vaccination. However, due to the absence of pathogenicity of the strain, it is not necessary to keep vaccinated animals separated from non–vaccinated animals.

Do not mix with any other veterinary medicinal product except EURICAN L. Following the administration of overdoses of vaccine, slight and transient pain and oedema may appear which regresses within 1 day.

# Special precautions to be taken by the person administering the medicinal product to animals

In case of accidental self-injection, seek medical advice immediately and show this package insert or the label to the physician.

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

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant approved for use by the competent authorities.

# 14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

MMM YYYY

# 15. OTHER INFORMATION

Type I glass vials with butyl-elastomer closure:

Bottle of 1 dose of freeze-dried pellet, box of 1 x 10 bottles.

Bottle of 1 dose of freeze-dried pellet, box of 1 x 50 bottles.

Bottle of 1 dose of freeze-dried pellet, box of 1 x 100 bottles.

Not all pack sizes may be marketed.

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