SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EURICAN P

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml dose of vaccine contains

Freeze-dried pellet:
Attenuated canine parvovirus ……..≥ $10^{4.9}$ $CCID_{50}$
Excipients qs 1 dose

$CCID_{50}$ = 50% cell culture infective dose.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate for suspension

4. CLINICAL PARTICULARS

4.1 Target species

Dogs and puppies from 8 weeks of age.

4.2 Indications for use specifying the target species

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.

4.3 Contra-indications

None.

4.4 Special warnings for each target species

None

4.5 Special precautions for use, including special precautions to be taken by the person administering the medicinal product to animals

i. Special precautions for use in animals

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.

ii. 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.

4.6 Adverse reactions (frequency and seriousness)

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.

4.7 Use during pregnancy, lactation or lay

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.

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 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 Eurican L. 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

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Following the administration of overdoses of vaccine, slight and transient pain and oedema may appear which regresses within 1 day.

4.11 Withdrawal periods

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

The vaccine stimulates active immunity against canine parvovirus.

ATC Vet Code: QI07AD01

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Freeze-drying substrate
PBS buffer

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product except Eurican L.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after reconstitution: Use immediately on reconstitution.

6.4 Special precautions for storage

Store and transport at + 2°C – + 8°C, protected from light. Do not freeze.

6.5 Nature and composition of immediate packaging

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.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

7 MARKETING AUTHORISATION HOLDER

Merial Animal Health Limited
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Sandringham House
Sandringham Avenue
Harlow Business Park
Harlow
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CM19 5TG
UK

8. MARKETING AUTHORISATION NUMBER(S)

Vm 08327/4151
VPA10857/56/1

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date: UK: 28 October 2005
Date: IE: 3 November 2004

10. DATE OF REVISION OF THE TEXT

Date: May 2012

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.