ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eurican Herpes 205 powder and solvent for emulsion for injection.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance :
Per 1-ml dose: Canine herpesvirus (F205 strain) antigens ..... 0.3 to 1.75 µg*
*expressed in µg of gB glycoproteins

Adjuvant:
Light paraffin oil ..... 224.8 to 244.1 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder and solvent for emulsion for injection
Lyophilisate : white pellet.
Solvent : homogeneous white emulsion

4. CLINICAL PARTICULARS

4.1 Target species

Dogs (pregnant bitches)

4.2 Indications for use, specifying the target species

Active immunisation of bitches to prevent mortality, clinical signs and lesions in puppies resulting from canine herpes virus infections acquired in the first few days of life through passive immunity.

4.3 Contraindications

None.

4.4 Special warnings

Abortion and premature parturition can occur as a result of CHV infection in bitches, the protection of the bitch against infection has not been studied for this vaccine. In order for immunity to be conferred to the puppies, sufficient intake of colostrum is required.

4.5 Special precautions for use

Special precautions for use in animals

Vaccinate only healthy animals.

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

To the user:
This veterinary medicinal product contains mineral oil. Accidental injection/self-injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given.
If you are accidentally injected with this product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you.
If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

4.6 Adverse reactions (frequency and seriousness)

The vaccine may commonly cause transient oedema at the site of injection. These reactions usually regress within one week.

Hypersensitivity reactions may occur. These are rare and appropriate symptomatic treatment should be administered.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

4.7 Use during pregnancy, lactation or lay

This vaccine is specifically indicated during pregnancy.

4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product.
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

Following reconstitution of the powder with the solvent, inject one dose (1ml) of the vaccine via the subcutaneous route, according to the following schedule:
First injection: Either during heat or 7 –10 days after the presumed date of mating.
Second injection: 1 to 2 weeks before the expected date of whelping.
Revaccination: during each pregnancy, according to the same schedule.

The reconstituted content shall be a milky emulsion.

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

No undesirable effects other than those mentioned in the “Adverse reactions” section have been observed after the administration of several doses.

4.11 Withdrawal period(s)

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group : Inactivated viral vaccines
ATCvet code: QI07AA06

Purified subunit vaccine for the active immunisation of pregnant bitches to induce passive immunity in puppies against herpesvirus-induced fatal neonatal disease.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Sorbitol
Dextran 40
Casein hydrolysate
Collagen hydrolysate
Salts
Polyoxyethylene fatty acids
Ether of fatty alcohols and of polyols
Triethanolamine

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product except the solvent supplied for use with the veterinary medicinal product.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 24 months.
Shelf life after reconstitution: use immediately

6.4 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).
Do not freeze.
Protect from light.

6.5 Nature and composition of immediate packaging

Type I glass bottle containing powder for 1-dose and glass bottle containing 1-ml of solvent.
The bottles are closed with a butyl elastomer closure and sealed with an aluminium cap
Box of 2 x 1 bottle, 2 x 10 bottles and 2 x 50 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

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

7. MARKETING AUTHORISATION HOLDER

MERIAL
29 Avenue Tony Garnier
69007 Lyon
FRANCE

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/01/029/001- 003

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26.03.2001
Date of last renewal: 18.04.2006

10. DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu.

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX II

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE(S) AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY OR USE

C. STATEMENT OF THE MRLs

A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE(S) AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer of the biological active substance(s)

MERIAL,
Laboratory of Lyon Gerland
254, Avenue Marcel Mérieux
69007 Lyon
France

MERIAL
Laboratoire Porte des Alpes
Rue de l'Aviation
69800 Saint Priest
France

Name and address of the manufacturer responsible for batch release

MERIAL
Laboratoire Porte des Alpes
Rue de l'Aviation
69800 Saint Priest
France

B. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION REGARDING SUPPLY OR USE

Veterinary medicinal product subject to prescription

C. STATEMENT OF THE MRLs

Not applicable.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box of 2 x 1 bottle, 2 x 10 bottles and 2 x 50 bottles

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eurican Herpes 205 powder and solvent for emulsion for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Per 1-ml dose: Canine herpesvirus (F205 strain) antigens ..... 0.3 to 1.75 µg*
*expressed in µg of gB glycoproteins
Light paraffin oil

3. PHARMACEUTICAL FORM

Powder and solvent for emulsion for injection.

4. PACKAGE SIZE

1 dose: powder (1 bottle) + solvent (1 bottle)
10 doses: powder (10 bottles) + solvent (10 bottles)
50 doses: powder (50 bottles) + solvent (50 bottles)

5. TARGET SPECIES

Dogs (pregnant bitches)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Accidental injection is dangerous

10. EXPIRY DATE

EXP {month/year}
Once reconstituted use immediately.

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator (2 °C – 8 °C).
Do not freeze.
Protect from light.

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

Read the package leaflet before use.

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

MERIAL
29 Avenue Tony Garnier
69007 Lyon
France

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/01/029/001 10 doses: powder (10 bottles) + solvent (10 bottles)
EU/2/01/029/002 50 doses: powder (50 bottles) + solvent (50 bottles)
EU/2/01/029/003 1 dose: powder (1 bottle) + solvent (1 bottle)

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eurican Herpes 205 powder for injection

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Read the 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

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP {month/year}
Once reconstituted use immediately.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eurican Herpes 205 solvent

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Read the 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

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP {month/year}
Once reconstituted use immediately.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
Eurican Herpes 205 powder and solvent for emulsion 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:
MERIAL, 29 Avenue Tony Garnier, 69007 Lyon, France

Manufacturer responsible for batch release:
MERIAL, Laboratoire Porte des Alpes, Rue de l'Aviation, 69800 Saint Priest, France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eurican Herpes 205 powder and solvent for emulsion for injection

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

Active substance:
Per 1-ml dose: Canine herpesvirus (F205 strain) antigens ..... 0.3 to 1.75 µg*
*expressed in µg of gB glycoproteins

Adjuvant:
Light paraffin oil ..... 224.8 to 244.1 mg

Lyophilisate : white pellet.
Solvent : homogeneous white emulsion

4. INDICATIONS

Active immunisation of bitches to prevent mortality, clinical signs and lesions in puppies resulting from canine herpes virus infections acquired in the first few days of life through passive immunity.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

Hypersensitivity reactions may occur. These are rare and appropriate symptomatic treatment should be administered.
The vaccine may commonly cause transient oedema at the site of injection. These reactions usually regress within one week.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)

- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

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

7. TARGET SPECIES

Dogs (pregnant bitches)

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

Following reconstitution of the powder with the solvent, inject one dose (1ml) of the vaccine via the subcutaneous route, according to the following schedule:
First injection: Either during heat or 7 –10 days after the presumed date of mating.
Second injection: 1 to 2 weeks before the expected date of whelping.
Revaccination: during each pregnancy, according to the same schedule.

9. ADVICE ON CORRECT ADMINISTRATION

Aseptically reconstitute the contents of the powder with the solvent supplied with this vaccine.

The reconstituted content shall be a milky emulsion.

10. WITHDRAWAL PERIOD

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children
Store in a refrigerator (2 °C – 8 °C).
Do not freeze.
Protect from light.
Once reconstituted use immediately.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after "EXP".

12. SPECIAL WARNING(S)

Special warnings for each target species:
Abortion and premature parturition can occur as a result of CHV infection in bitches, the protection of the bitch against infection has not been studied for this vaccine. In order for immunity to be conferred to the puppies, sufficient intake of colostrum is required

Special precautions for use in animals:
Vaccinate only healthy animals.

Special precautions to be taken by the person administrating the veterinary medicinal product to animals:
To the user:
This product contains mineral oil. Accidental injection/self injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given.
If you are accidentally injected with this product, seek prompt medical advice even if only a very small amount is injected and take the package insert with you.
If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:
This product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

Pregnancy:
This vaccine is specifically indicated during pregnancy.

Overdose:
No undesirable effects other than those-mentioned in the "Adverse reactions" section have been observed after the administration of several doses.

Incompatibilities:
Do not mix with any other veterinary medicinal product except the solvent supplied for use with the veterinary medicinal product.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. 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.

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 the local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this product is available on the website of the European Medicines Agency http://www.ema.europa.eu.

15. OTHER INFORMATION

Purified subunit vaccine for the active immunisation of pregnant bitches to induce passive immunity in puppies against herpesvirus-induced fatal neonatal disease.

Box of 2 x 1 bottle, 2 x 10 bottles and 2 x 50 bottles.
Not all pack sizes may be marketed.
To be supplied only on veterinary prescription.