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

Per 1 ml dose:

Lyophilisate :
Active substance:

Canine herpesvirus (F205 strain) antigens	0.3 to 1.75 µg*

*expressed in µg of gB glycoproteins

Solvent**:**
Adjuvant:

Light paraffin oil	224.8 to 244.1 mg

Excipients:

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.

4.2 Indications for use, specifying the target species

Active immunisation of pregnant 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 for each target species

Vaccinate healthy animals only.
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
None.

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 rarely occur. 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 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).

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 (1 ml) of the vaccine via the subcutaneous route, according to the following schedule:

First injection: Either during heat or 7 to 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 4.6 have been observed after the administration of several doses.

4.11 Withdrawal period(s)

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: immunologicals for dogs, inactivated viral vaccines, canine herpesvirus
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

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

6.2 Major 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: 2 years.
Shelf life after reconstitution according to directions: 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 1ml 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

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

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

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. STATEMENT OF THE MRLs

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

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

Boehringer Ingelheim Animal Health France SCS
Laboratoire Porte des Alpes
Rue de l'Aviation
69800 Saint Priest
France

Name and address of the manufacturer responsible for batch release

Boehringer Ingelheim Animal Health France SCS
Laboratoire Porte des Alpes
Rue de l'Aviation
69800 Saint Priest
France

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND 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 SUBSTANCES

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

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

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

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.
Do not freeze.
Protect from light.

12. SPECIAL 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 Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

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 (Glass) vaccine

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(S)

6. BATCH NUMBER

Lot {number}

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

Bottle1 ml solvent

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(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 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:
Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

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 Herpes 205 powder and solvent for emulsion for injection

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

Per 1 ml dose:

Lyophilisate **:**
Active substance:
Canine herpesvirus (F205 strain) antigens 0.3 to 1.75 µg*
*expressed in µg of gB glycoproteins

Solvent:
Adjuvant: Light paraffin oil 224.8 to 244.1 mg

Lyophilisate: white pellet.
Solvent: homogeneous white emulsion

4. INDICATIONS

Active immunisation of pregnant 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

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

Hypersensitivity reactions may rarely occur. 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 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 serious effects or other effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs.

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

Following reconstitution of the powder with the solvent, inject one dose (1 ml) of the vaccine via the subcutaneous route, according to the following schedule:

First injection: Either during heat or 7 to 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(S)

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.
Shelf life after reconstitution according to directions: 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:
Vaccinate healthy animals only.
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:
None.

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 and lactation:
This vaccine is specifically indicated during pregnancy.

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.

Overdose (symptoms, emergency procedures, antidotes):
No adverse effects other than those listed in section “Adverse reactions” 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.

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

Medicines should not be disposed of via wastewater or household waste. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Detailed information on this veterinary medicinal 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.