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 mcg*
*expressed in mcg of gB glycoproteins

Solvent**:**
Adjuvant:
Light paraffin oil 224.8 to 244.1 mg

Excipients:

Qualitative composition of excipients and other constituents
Lyophilisate:
Sucrose
Sorbitol
Dextran 40
Casein hydrolysate
Collagen hydrolysate
Salts
Water for injections
Solvent:
Polyoxyethylene fatty acids
Ether of fatty alcohols and of polyols
Triethanolamine
Salts
Water for injections

Lyophilisate: white pellet.
Solvent: homogeneous white emulsion.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each 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.

Onset of immunity: the passive immunity in puppies born from vaccinated bitches starts with sufficient colostrum intake.

Duration of immunity: first few days of life.

3.3 Contraindications

None.

3.4 Special warnings

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.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Not applicable.

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 veterinary medicinal 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 veterinary medicinal 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.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Dogs:

Common (1 to 10 animals / 100 animals treated):	Injection site swelling.[1]
Rare (1 to 10 animals / 10 000 animals treated):	Hypersensitivity reaction.[2]

[1] Transient. Usually regressing within one week.
[2] Appropriate symptomatic treatment should be administered.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
This vaccine is specifically indicated during pregnancy.

3.8 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.

3.9 Administration routes and dosage

Subcutaneous route.

Following reconstitution of the powder with the solvent, inject one dose (1 ml) of the vaccine 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No undesirable effects other than those mentioned in the “Adverse events” section 3.6 have been observed after the administration of a 2-fold overdose .

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. IMMUNOLOGICAL INFORMATION

4.1 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after reconstitution according to directions: use immediately.

5.3 Special precautions for storage

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

5.4 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.

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

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/01/029/001-003

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 26/03/2001

9. DATE OF THE LAST REVISION OF THE SUMMARY OF PRODUCT CHARACTERISTICS

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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