

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 mcg*
*expressed in mcg of gB glycoproteins	

Solvent:

Adjuvant:

Light paraffin oil	224.8 to 244.1 mg
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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.

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.

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

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 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.

Special precautions for the protection of the environment

Not applicable.

Other precautions

Not applicable.

4.6 Adverse reactions (frequency and seriousness)

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 of the package leaflet for respective contact details.

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 Amount(s) to be administered and administration route

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.

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 a 2-fold overdose.

4.11 Withdrawal period(s)

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for Canidae, 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
Water for injections

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 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 local requirements.

7. MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

8. MARKETING AUTHORISATION NUMBER

Vm 04491/5008

9. DATE OF FIRST AUTHORISATION

26 March 2001

10. DATE OF REVISION OF THE TEXT

November 2024

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk.

Approved 20 November 2024
Gavin Hall