

Biofel PCH

emulsion for injection for cats

Vaccine against feline panleukopenia, calicivirus and herpesvirus infection

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE
 Bioveta, a. s., Komenského 212,
 683 23 Ivanovice na Hané, Czech Republic

2. NAME OF THE VETERINARY MEDICINAL PRODUCT
 Biofel PCH emulsion for injection for cats
 Vaccine against feline panleukopenia, calicivirus and herpesvirus infection

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

Composition - 1 ml (1 dose):

Active substances:

Virus panleukopeniae contagiosae felis inactivatum	RP ≥ 1
Calicivirus felis inactivatum	RP ≥ 1
Herpesvirus felis inactivatum	RP ≥ 1

* RP = Relative potency (ELISA test) compared with the reference serum obtained after vaccination of guinea pigs with a vaccine batch that has successfully passed the challenge test on the target species.

Excipients:	
Thiomersal	0.01 %
Adjuvants:	
Oil adjuvant (Emulsigen)	ad 1 ml

4. INDICATION

For active immunisation against feline panleukopenia, calicivirus and herpesvirus infection.

The onset of protective immunity against panleukopenia is established at 3 weeks after basic vaccination and the onset of protective immunity against feline calicivirus and herpesvirus infection is established at 4 weeks after basic vaccination.

The duration of immunity is 12 months.

5. CONTRAINDICATIONS

Do not use in case of general febrile illness.

6. ADVERSE REACTIONS

An adequate local reaction (usually the size of a pea) may appear at the administration site, which disappears within 3 weeks. Vaccination may exceptionally cause hypersensitivity reactions. In such case, appropriate treatment should be initiated immediately.

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

7. TARGET SPECIES

Cats

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

Dose - 1 ml regardless of age, weight and breed of the individual, but not earlier than at 8 weeks of age.
 Method of administration - subcutaneous, preferably in the region behind the shoulder blade.

Vaccination schedule:

Basic vaccination:
 Two administrations at an interval of 3 weeks.
 The first vaccination with one dose of Biofel PCH in kittens from the age of 8 - 10 weeks and the second vaccination with one dose of Biofel PCH from the age of 3 months.
 Revaccination:
 Further regular revaccination with Biofel PCH is carried out in 12-month intervals.

9. ADVICE ON CORRECT ADMINISTRATION

The vial contents should be shaken well before use.

10. WITHDRAWAL PERIOD

Not intended for food-producing animals.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
 Store in a refrigerator (2 °C - 8 °C).
 Protect from light.
 Protect from frost.

Shelf life after first opening the immediate packaging: 8 hours.

Do not use this veterinary medicinal product after the expiry date which is stated on the label.

12. SPECIAL WARNINGS

Special warnings for each target species
 Vaccinate only clinically healthy individuals in good nutritional condition.
 Any antiparasitic treatment should precede the vaccination by at least 10 days.

Use during pregnancy, lactation or lay
 Vaccination of pregnant cats is recommended in the first half of pregnancy.

Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy of this vaccine when administered concurrently with other veterinary medicinal products.
 Decision about using this vaccine before or after any other veterinary medicinal product must be based on consideration of individual cases.

Incompatibilities

Do not mix with other veterinary medicinal products.

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

To the user:

This product contains mineral oil. Accidental injection/self-injection with the product may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases can lead to loss of the affected finger if not given prompt medical attention.

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 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.

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 product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

December 2014

15. OTHER INFORMATION

For animal treatment only.

Veterinary medicinal product subject to prescription.

Package size:

2 × 1 dose, 10 × 1 dose, 20 × 1 dose, 100 × 1 dose, 1 × 5 doses, 5 × 5 dose, 10 × 5 doses

Not all pack sizes may be marketed.

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