

**B. PACKAGE LEAFLET**

**PACKAGE LEAFLET:**  
Biofel PCHR emulsion for injection for cats

**1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

Marketing authorisation holder and manufacturer responsible for batch release:  
Bioveta, a. s., Komenského 212/12, 683 23 Ivanovice na Hané, Czech Republic

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Biofel PCHR emulsion for injection for cats

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

Composition - 1 ml (1 dose):

**Active substances:**

Inactivated feline panleucopeniavirus, strain FPV Bio 7	RP $\geq$ 1*
Inactivated feline calicivirus, strain FCV F9 Bio 8	RP $\geq$ 1*
Inactivated feline herpesvirus, strain FHV-1 Bio 9	RP $\geq$ 1*
Inactivated Rabies virus, strain SAD Vnukovo-32	min 1 IU

\*) 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.

**Adjuvant:**

Oil adjuvant (Emulsigen) ad 1 ml

**Excipient:**

Thiomersal 0.01%

The vaccine is an oily pinkish liquid without any sediment.

**4. INDICATION(S)**

For active immunisation of cats from the age of 3 months against feline panleukopenia, herpesvirus and calicivirus infection and rabies.

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 and rabies is established at 4 weeks after basic vaccination.

The duration of immunity is 12 months.

**5. CONTRAINDICATIONS**

None

**6. ADVERSE REACTIONS**

Following subcutaneous administration in cats a transient swelling (usually up to 0.5 cm in diameter) and painfulness which disappears within 3 weeks may very rarely be observed at the injection site. Apathy and anorexia may occur in very rare cases. Transient increase of temperature is very rare after vaccination. In very rare cases hypersensitivity reactions may occur. In such case, appropriate treatment should be initiated without delay.

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 side 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**

Cats.

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

Dose - 1 ml regardless of age, weight and breed of the individual, but not earlier than at three months of age.

Method of administration - subcutaneous, preferably in the region behind the shoulder blade.

Vaccination schedule:

Basic vaccination:

One dose of Biofel PCHR from 3 months of age, after a previous administration of one dose of Biofel PCH in kittens aged 8 – 10 weeks.

The recommended interval between doses is 3 – 4 weeks.

Revaccination:

Further regular revaccination with Biofel PCHR is carried out in 12-month intervals.

## **9. ADVICE ON CORRECT ADMINISTRATION**

The vial contents should be shaken well before use.

## **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).

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 after EXP.

## **12. SPECIAL WARNING(S)**

### Special warnings for each target species

Vaccinate healthy animals only. Any antiparasitic treatment should precede the vaccination by at least 10 days.

Effect of maternal antibodies on the vaccine efficacy has not been studied.

### Pregnancy:

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 used with any other veterinary medicinal products. 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.

### 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**

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

## **14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

## **15. OTHER INFORMATION**

### **Package size:**

2 x 1 dose, 10 x 1 dose, 20 x 1 dose, 100 x 1 dose,

1 x 5 doses, 5 x 5 doses, 10 x 5 doses

Not all pack sizes may be marketed.

For animal treatment only.

Veterinary medicinal product subject to prescription.