ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Biofel PCHR emulsion for injection for cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition - 1 ml (1 dose):

Active substances:

Inactivated feline panleucopenia virus, strain FPV Bio 7	RP ≥ 1*
Inactivated feline calicivirus, strain FCV F9 Bio 8	RP ≥ 1*
Inactivated feline herpesvirus, strain FHV-1 Bio 9	RP ≥ 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%

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Emulsion for injection.
Pinkish liquid without any sediment.

4. CLINICAL PARTICULARS

4.1 Target species

Cats.

4.2 Indications for use, specifying the target species

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.

4.3 Contraindications

None

4.4 Special warnings for each target species

Any antiparasitic treatment should precede the vaccination by at least 10 days.
Effect of maternal antibodies on the vaccine efficacy has not been studied.
Vaccinate healthy animals only.

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 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.

4.6 Adverse reactions (frequency and seriousness)

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).

4.7 Use during pregnancy, lactation or lay

Vaccination of pregnant cats is recommended in the first half of 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 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.

4.9 Amounts to be administered and administration route

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.
The vial contents should be shaken well before use.

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

A double dose of the vaccine has no other side effects on the target species than those listed in section 4.6.

4.11 Withdrawal period(s)

Not applicable.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Inactivated viral vaccines for cats
ATC classification: QI06AA09 Vaccine against feline viral panleukopenia, feline calicivirosis, feline viral rhinotracheitis and rabies.

After application to the body of a vaccinated individual, the antigens in the vaccine is recognized as foreign and a number of defence mechanisms of the body are activated (macrophages, opsonins, interleukins, B lymphocytes, etc.), which results in formation of specific antibodies against the antigenic determinants contained in the vaccine. These mechanisms should prevent the subsequent development of infection.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Thiomersal
Oil adjuvant (Emulsigen).

6.2 Major incompatibilities
Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 8 hours.

6.4. Special precautions for storage

Store in a refrigerator (2 °C – 8 °C).
Protect from frost.
Protect from light.

6.5 Nature and composition of immediate packaging

The vaccine is filled into glass vials of hydrolytic class I, sealed with pierceable rubber stoppers and secured with aluminium caps.

The product is delivered in the following pack sizes:
A/ Plastic box with a lid, with 10 wells: 2 x 1 dose, 10 x 1 dose, 5 x 5 doses,
10 x 5 doses

B/ Plastic box with a lid, with 20 wells: 20 x 1 dose
C/ Plastic box with a lid, with 100 wells: 100 x 1 dose
D/ Carton: 1 x 5 doses

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 product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Bioveta, a.s., Komenského 212/12, 683 23, Ivanovice na Hané, Czech Republic

8. MARKETING AUTHORISATION NUMBER(S)

97/004/06-C

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01/06/2006
Date of last renewal: 15/12/2011

10 DATE OF REVISION OF THE TEXT

April 2019