

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE**

**carton box:**

1x5 doses

**shawl etiquette:**

a/ plastic box with cap with 10 holes: 2 x 1 dose, 10 x 1 dose, 5 x 5 doses, 10 x 5 doses

b/ plastic box with cap with 20 holes: 20 x 1 dose

c/ plastic box with cap with 100 holes: 100 x 1 dose

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

Biofel PCH emulsion for injection for cats

**2. STATEMENT OF ACTIVE SUBSTANCES**

Composition - 1 ml (1 dose):

Inactivated feline panleucopeniavirus

RP  $\geq$  1

Inactivated feline calicivirus

RP  $\geq$  1

Inactivated feline herpesvirus

RP  $\geq$  1

**3. PHARMACEUTICAL FORM**

Emulsion for injection.

**4. PACKAGE SIZE**

5 doses

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

**5. TARGET SPECIES**

Cats.

**6. INDICATION(S)**

-

**7. METHOD AND ROUTE(S) OF ADMINISTRATION**

Subcutaneous use.

Read the package leaflet before use.

**8. WITHDRAWAL PERIOD(S)**

Withdrawal period: Not applicable.

**9. SPECIAL WARNING(S), IF NECESSARY**

Read the package leaflet before use.

**10. EXPIRY DATE**

EXP {month/year}

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

**11. SPECIAL STORAGE CONDITIONS**

Store in a refrigerator.

Protect from frost.

Protect from light.

**12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY**

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE**

For animal treatment only - to be supplied only on veterinary prescription.

**14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the reach and sight of children.

**15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

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

**16. MARKETING AUTHORISATION NUMBER(S)**

**17. MANUFACTURER’S BATCH NUMBER**

Batch {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

1 dose (1 ml)

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

Biofel PCH

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

**3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

1 dose

**4. ROUTE(S) OF ADMINISTRATION**

SC

**5. WITHDRAWAL PERIOD(S)**

-

**6. BATCH NUMBER**

Batch:

**7. EXPIRY DATE**

EXP:

**8. THE WORDS "FOR ANIMAL TREATMENT ONLY"**

For animal treatment only.

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

5 dose

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

Biofel PCH

**2. QUANTITY OF THE ACTIVE SUBSTANCE(S)**

Composition - 1 ml (1 dose):

Inactivated feline panleucopeniavirus

RP  $\geq$  1

Inactivated feline calicivirus

RP  $\geq$  1

Inactivated feline herpesvirus

RP  $\geq$  1

**3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES**

5 dose

**4. ROUTE(S) OF ADMINISTRATION**

SC

**5. WITHDRAWAL PERIOD(S)**

-

**6. BATCH NUMBER**

Batch:

**7. EXPIRY DATE**

EXP:

**8. THE WORDS "FOR ANIMAL TREATMENT ONLY"**

For animal treatment only.