

Medicinal product no longer authorised

**ANNEX I**

**SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fevaxyn Pentofel, suspension for injection for cats

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per dose of 1 ml (single dose syringe):

Active components	Relative potency (R.P.)
Inactivated feline panleucopenia virus, strain CU4	≥ 8.50
Inactivated feline calicivirus, strain 255	≥ 1.26
Inactivated feline rhinotracheitis virus, strain 605	≥ 1.39
Inactivated <i>Chlamydomphila felis</i> , strain Cello	≥ 1.69
Inactivated feline leukaemia virus, strain 61E	≥ 1.45
<b>Adjuvants</b>	
Ethylene/maleic anhydride (EMA-31)	1% (v/v)
Neocryl	3% (v/v)
Emulsigen SA	5% (v/v)

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Suspension for injection.

Vaccine appearance is a pale milky pink liquid which should be free from solid particles.

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Cats.

### 4.2 Indications for use, specifying the target species

For the active immunisation of healthy cats 9 weeks or older against feline panleucopenia and feline leukaemia viruses and against respiratory diseases caused by feline rhinotracheitis virus, feline calicivirus and *Chlamydomphila felis*.

### 4.3 Contraindications

None.

### 4.4 Special warnings for each target species

Vaccination does not affect the course of feline leukaemia virus (FeLV) infection in cats already infected with FeLV at the time of vaccination, implying that such cats will excrete FeLV irrespective of vaccination; consequently, these animals will constitute a hazard to susceptible cats in their environment. It is therefore recommended that cats with a significant risk of having been exposed to FeLV be tested for FeLV antigen prior to vaccination. Test negative animals can be vaccinated, while test-positive cats should be isolated from other

cats and retested within 1–2 months. Cats positive at the second testing should be considered as being permanently infected with FeLV and should be handled accordingly. Cats negative at second testing can be vaccinated since, in all likelihood, they have overcome the FeLV infection.

#### 4.5 Special precautions for use

##### Special precautions for use in animals

In case of anaphylactoid reaction, adrenaline should be administered intramuscularly. Vaccination of FeLV positive cats is of no benefit. See section 4.4 for further details.

##### 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 veterinary medicinal 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.

#### 4.6 Adverse reactions (frequency and seriousness)

Vaccinated cats may develop post-vaccinal reactions including transient fever, vomiting, anorexia and/or depression which usually disappear within 24 hours.

A local reaction with swelling, pain, pruritus or hair loss at the injection site may be observed.

Anaphylactic reactions with oedema, pruritus, respiratory and cardiac distress, severe gastrointestinal signs (including haematemesis and haemorrhagic diarrhoea) or shock have been seen during the first hours after vaccination in very rare cases. See section 4.5 for guidance about treatment.

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

##### Pregnancy:

The safety of the vaccine in pregnant queens has not been investigated. Vaccination of pregnant queens is not recommended.

#### **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 decided on a case by case basis.

#### **4.9 Amounts to be administered and administration route**

The contents of the single dose syringe should be shaken well and administered aseptically by subcutaneous injection. When administering the product, care must be taken to attach the enclosed sterile needle aseptically to the syringe before use.

*Basic vaccination* of cats 9 weeks and older: two doses at an interval of 3 to 4 weeks. An additional dose is recommended for kittens living in high-risk FeLV environments whose first dose was administered before 12 weeks of age.

*Revaccination:* one vaccination annually.

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

No undesirable effects other than those observed and mentioned in section 4.6 “Adverse reactions” have been observed.

#### **4.11 Withdrawal period(s)**

Not applicable.

### **5. IMMUNOLOGICAL PROPERTIES**

Pharmacotherapeutic group: immunologicals for felidae, inactivated viral and inactivated bacterial vaccines for cats.

ATC vet code: QI06AL01.

Fevaxyn Pentofel stimulates the development of active immunity against feline panleucopenia virus, feline rhinotracheitis virus, feline calicivirus, *Chlamydomphila felis* and feline leukaemia virus.

### **6. PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Eagles Earles Medium with Hepes

#### **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.

#### **6.4 Special precautions for storage**

Store and transport refrigerated (2 °C – 8 °C).

Do not freeze.

Protect from light.

#### **6.5 Nature and composition of immediate packaging**

Single dose disposable Type I glass syringes containing one dose (1 ml) of vaccine. The syringes are sealed with rubber tips.

Packaging:

One cardboard box containing 10, 20 or 25 single dose (1 ml) pre-filled syringes and 10, 20 or 25 sterile needles respectively.

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 product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with national requirements.

### **7. MARKETING AUTHORISATION HOLDER**

Zoetis Belgium SA  
Rue Laid Burniat 1  
1348 Louvain-la-Neuve  
BELGIUM

### **8. MARKETING AUTHORISATION NUMBER(S)**

EU/2/96/002/001-003

### **9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 5 February 1997.

Date of last renewal: 27 February 2007.

### **10. DATE OF REVISION OF THE TEXT**

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (<http://www.ema.europa.eu/>).

### **PROHIBITION OF SALE, SUPPLY AND/OR USE**

Not applicable.

**ANNEX I**

- A. MANUFACTURERS OF THE BIOLOGICAL ACTIVE SUBSTANCES AND MANUFACTURERS RESPONSIBLE FOR BATCH RELEASE**
- B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY OR USE**
- C. STATEMENT OF THE MRLs**

**A. MANUFACTURERS OF THE BIOLOGICAL ACTIVE SUBSTANCES AND  
MANUFACTURERS RESPONSIBLE FOR BATCH RELEASE**

Name and address of the manufacturers of the biological active substances

Zoetis Belgium SA  
Rue Laid Burniat 1  
1348 Louvain-la-Neuve  
BELGIUM

Name and address of the manufacturers responsible for batch release

Zoetis Belgium SA  
Rue Laid Burniat 1  
1348 Louvain-la-Neuve  
BELGIUM

**B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY OR USE**

Veterinary medicinal product subject to prescription.

**C. STATEMENT OF THE MRLs**

Not applicable.

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**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**



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**A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**BOX OF 10 x 1 ML SINGLE DOSE SYRINGES, 20 x 1 ML SINGLE DOSE SYRINGES, 25 x 1 ML SINGLE DOSE SYRINGES**

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

Fevaxyn Pentofel suspension for injection for cats

**2. STATEMENT OF ACTIVE SUBSTANCES**

Per dose of 1 ml:  
Inactivated FPV / FCV / FVR / Chlam / FeLV.

Adjuvant: mineral oil.

**3. PHARMACEUTICAL FORM**

Suspension for injection.

**4. PACKAGE SIZE**

10 x 1 ml single dose syringes  
20 x 1 ml single dose syringes  
25 x 1 ml single dose syringes

**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)**

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

Read the package leaflet before use.

Accidental injection is dangerous.

**10. EXPIRY DATE**

EXP {month/year}

**11. SPECIAL STORAGE CONDITIONS**

Store and transport refrigerated.

Do not freeze.

Protect from light.

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

Disposal: read package leaflet.

**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 sight and reach of children.

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

Zoetis Belgium SA  
Rue Laid Burniat 1  
1348 Louvain-la-Neuve  
BELGIUM

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

EU/2/96/002/001	10 x 1 ml
EU/2/96/002/002	20 x 1 ml
EU/2/96/002/003	25 x 1 ml

**17. MANUFACTURER'S BATCH NUMBER**

Lot {number}

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

**SINGLE DOSE SYRINGE**

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

Fevaxyn Pentofel for cats

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

FPV / FCV / FVR / Chlam / FeLV

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

1 ml

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

SC

**5. WITHDRAWAL PERIOD(S)**

**6. BATCH NUMBER**

Lot {number}

**7. EXPIRY DATE**

EXP {month/year}

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

For animal treatment only.

Medicinal product no longer authorised

**B. PACKAGE LEAFLET**

**PACKAGE LEAFLET:**  
**Fevaxyn Pentofel, suspension 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:

Zoetis Belgium SA  
Rue Laid Burniat 1  
1348 Louvain-la-Neuve  
BELGIUM

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

Fevaxyn Pentofel, suspension for injection for cats

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

Per dose of 1 ml (single dose syringe):

<b>Active components</b>	<b>Relative potency (R.P.)</b>
Inactivated feline panleucopenia virus, strain CU4	≥ 8.50
Inactivated feline calicivirus, strain 255	≥ 1.26
Inactivated feline rhinotracheitis virus, strain 605	≥ 1.39
Inactivated <i>Chlamydomphila felis</i> , strain Cefo	≥ 1.69
Inactivated feline leukaemia virus, strain 61E	≥ 1.45
<b>Adjuvants</b>	
Ethylene/maleic anhydride (EMA-21)	1% (v/v)
Neocryl	3% (v/v)
Emulsigen SA	5% (v/v)

**4. INDICATION(S)**

For the active immunisation of healthy cats 9 weeks or older against feline panleucopenia and feline leukaemia viruses and against respiratory diseases caused by feline rhinotracheitis virus, feline calicivirus and *Chlamydomphila felis*.

**5. CONTRAINDICATIONS**

None

**6. ADVERSE REACTIONS**

Vaccinated cats may develop post-vaccinal reactions including transient fever, vomiting, anorexia and/or depression which usually disappear within 24 hours.

A local reaction with swelling, pain, pruritus or hair loss at the injection site may be observed.

Anaphylactic reactions with oedema, pruritus, respiratory and cardiac distress, severe gastrointestinal signs (including haematemesis and haemorrhagic diarrhoea) or shock have been seen during the first hours after vaccination in very rare cases.

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**

1 ml. Subcutaneous use.

*Primary vaccination* of cats 9 weeks and older: two doses at an interval of 3 to 4 weeks. An additional dose is recommended for kittens living in high-risk feline leukaemia virus (FeLV) environments whose first dose was administered before 12 weeks of age.

*Revaccination*: one vaccination annually.

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

The contents of the single dose syringe should be shaken well and administered aseptically by subcutaneous injection. When administering the product, care must be taken to attach the enclosed sterile needle aseptically to the syringe before use.

## **10. WITHDRAWAL PERIOD(S)**

Not applicable.

## **11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the sight and reach of children.

Store and transport refrigerated (2 °C – 8 °C).

Protect from light.

Do not freeze.

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:

Vaccination does not affect the course of FeLV infection in cats already infected with FeLV at the time of vaccination, implying that such cats will excrete FeLV irrespective of vaccination; consequently, these animals will constitute a hazard to susceptible cats in their environment. It is therefore recommended that cats with a significant risk of having been exposed to FeLV be tested for FeLV antigen prior to vaccination. Test negative animals can be vaccinated, while test-positive cats should be isolated from other cats and retested within 1–2 months. Cats positive at the second testing should be considered as being permanently infected with FeLV and should be handled accordingly. Cats negative at second testing can be vaccinated since, in all likelihood, they have overcome the FeLV infection.

### Special precautions for use in animals:

In case of an anaphylactoid reaction, adrenaline should be administered intramuscularly. Vaccination of FeLV positive cats is of no benefit.

### 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 veterinary medicinal 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.

#### Pregnancy:

The safety of the vaccine in pregnant queens has not been investigated. Vaccination of pregnant queens is not recommended.

#### 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 decided on a case by case basis.

#### Overdose (symptoms, emergency procedures, antidotes):

No undesirable effects other than those mentioned in section 6 have been observed.

#### Incompatibilities:

Do not mix with any other veterinary medicinal product.

## **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**

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (<http://www.ema.europa.eu/>).

**15. OTHER INFORMATION**

10 x 1 ml presentation: Box containing 10 single dose prefilled syringes and 10 sterile needles.

20 x 1 ml presentation: Box containing 20 single dose prefilled syringes and 20 sterile needles.

25 x 1 ml presentation: Box containing 25 single dose prefilled syringes and 25 sterile needles.

Not all pack sizes may be marketed.

Medicinal product no longer authorised