ANNEX III

LABELLING AND PACKAGE LEAFLET

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 UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER

Vm 42058/5027

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

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.

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):

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

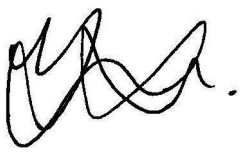
14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

TBC

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.



Approved: 24 June 2022