

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Fevaxyn Quatrifel Suspension for injection for cats

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Per dose of 1ml:

Active substances	Relative Potency (R.P.)*
Inactivated feline panleucopenia virus, strain CU4	8.50 - 12.25
Inactivated feline calicivirus, strain 255	1.26 - 2.40
Inactivated feline rhinotracheitis virus, strain 605	1.39 - 2.10
Inactivated <i>Chlamydophila felis</i> , strain Cello	1.69 - 3.50
Adjuvant	
Ethylene/maleic anhydride (EMA)	1% (v/v)
Neocryl	3% (v/v)
Emulsigen SA	5% (v/v)

Excipients:

For the full list of excipients see section 6.1.

* R.P.= Relative Potency (by in-vitro assay)

3 PHARMACEUTICAL FORM

Suspension for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Cats from 8 weeks of age.

4.2 Indications for use, specifying the target species

For the active immunisation of healthy cats 8 weeks or older to reduce clinical symptoms of disease caused by Feline Panleucopenia infection and to reduce clinical symptoms of respiratory diseases caused by Feline Rhinotracheitis virus, Feline Calicivirus and *Chlamydophila felis*.

Onset of immunity is from 2 weeks after completion of the primary vaccination course.
The duration of immunity lasts up to at least one year following the primary vaccination course.

4.3 Contraindications

None known.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Should an allergic reaction occur for any reason, intra-muscular adrenaline should be administered. In any animal population, a small number of individuals may fail to respond to vaccination. Only healthy, immune competent cats should be vaccinated.

Special precautions to be taken by the person administering the product to animals

To the user:

This 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 product, seek prompt medical advice even if only a very small amount is injected and take the package insert 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)

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 also be observed. Some vaccinates may also suffer mild conjunctivitis and/or ocular discharge (less than 0.0001%) which may occur up to two weeks after vaccination.

In very rare cases, an anaphylactoid reaction with oedema, pruritus, respiratory and cardiac distress, severe gastrointestinal signs or shock have been seen during the first hours after vaccination. See Section 4.5 (Special Precautions for use) for guidance about treatment.

4.7 Use during pregnancy, lactation or lay

Do not use during pregnancy.

4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the compatibility of this vaccine with any other. Therefore the safety and efficacy of this product when used with any other (either when used on the same day or at different times) has not been demonstrated.

4.9 Amounts to be administered and administration route

The contents of the pre-filled 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.

Dose: 1ml

Basic vaccination scheme

Cats Aged 8 Weeks and Older

For an initial vaccination course, two doses are required, injected at an interval of 3 to 4 weeks.

Re-vaccination scheme

Boost annually with a single dose of vaccine.

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

No undesirable effects other than those mentioned in section 4.6 have been observed.

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATC VET code: QI06AL02

Fevaxyn Quatrifel stimulates the development of active immunity against Feline Panleukopenia Virus, Feline Rhinotracheitis Virus, Feline Calicivirus and *Chlamydophila felis*.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Eagles Earles medium*

*containing 0.05% lactalbumin hydrosylate

6.2 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: 12 months

6.4 Special precautions for storage

Store in a refrigerator (2°C - 8°C). Protect from light. Do not freeze.

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 (1ml) 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 products or waste materials

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

Zoetis Ireland Limited
25/28 North Wall Quay
Dublin 1
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10438/054/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26th August 2011

Renewal of the last authorisation: 27th June 2009

10 DATE OF REVISION OF THE TEXT

May 2015