1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Leucogen

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (1.0 ml) contains:

Active substance:

FeLV recombinant p45 antigen	Minimum:	97	micrograms
	Target	102	micrograms

Adjuvant:

Aluminium hydroxide gel (3%)	0.1	ml
Quil A	10	micrograms

Excipients:
For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Suspension for injection

4 CLINICAL PARTICULARS

4.1 Target Species

Cats.

4.2 Indications for use, specifying the target species

For active immunisation of healthy cats to prevent persistent feline leukaemia-virus viraemia and any associated clinical signs of feline leucocis.

The onset of protection begins 2 weeks after immunisation and the duration of protection lasts one year after the basic vaccination.

4.3 Contraindications

Refer to Section 4.7.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals
The vaccine should be administered in accordance with the usual aseptic conditions for vaccination.

Vaccinate only healthy animals.

It is recommended that animals be treated for intestinal parasites at least 10 days prior to vaccination.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
In the case of accidental self-injection, seek medical advice immediately and show the package insert or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

Transient and small thickening or nodule, approximately 5-10 mm in size, may be observed at the injection site and disappear within 2 to 6 weeks without treatment. Occasionally, systemic reactions (hyperthermia, anorexia, lethargy) may occur within one or two days after vaccine administration.

4.7 Use during pregnancy, lactation or lay

In the absence of supporting data, the vaccine should not be used in pregnant or lactating cats.

4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy from the concurrent use of this vaccine with any other except Feligen RCP, where this vaccine is authorised. It is therefore recommended that no other vaccine than Feligen RCP should be administered within 14 days before or after vaccination with Leucogen.

4.9 Amounts to be administered and administration route

Shake the vial before use. Administer Leucogen via the subcutaneous route to cats according to the following regimen of vaccination:

Basic Vaccination Scheme:
Dose 1: A single 1 ml dose from a minimum of 8 weeks of age.
Dose 2: A single 1 ml dose 3 to 4 weeks later.

Re-vaccination Scheme:
Administer a single 1 ml dose on an annual basis thereafter.

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

No undesirable effects have been seen after the administration of an overdose of Leucogen except those indicated in Section 4.6 Adverse Effects.

4.11 Withdrawal period(s)

Not applicable

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

To stimulate active immunity to feline leucosis
ATC Vet code**:** QI06AA01

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium phosphate anhydrous
Potassium dihydrogen phosphate
Sodium chloride
Water for injection

6.2 Incompatibilities

Do not mix with any other vaccine / immunological product except Feligen RCP, where this vaccine is authorised.

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).
Protect from light. Do not freeze.

6.5 Nature and composition of immediate packaging

Glass vial containing the vaccine and closed with a 13 mm diameter rubber stopper and sealed with an aluminium seal.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, where appropriate

Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Virbac S.A. 1ère avenue
2065 M LID
06516 Carros
France

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10988/40/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21st September 2007

10 DATE OF REVISION OF THE TEXT