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Nobivac LeuFel (*feline leukaemia inactivated vaccine*)

An overview of Nobivac LeuFel and why it is authorised in the EU

What is Nobivac LeuFel and what is it used for?

Nobivac LeuFel is a veterinary vaccine used in cats from eight weeks of age to protect them against feline leukaemia. Feline leukaemia is an infectious disease of cats which affects the immune system and is caused by the feline leukaemia virus (FeLV). Signs of the disease can include loss of appetite, weight loss, poor fur condition, fever, pale gums and diarrhoea; cats persistently infected with the virus may spread it to other cats. The vaccine is used to prevent the disease signs and persistent viraemia (the presence of FeLV in the blood).

The medicine contains a protein from the outer layer of FeLV.

This medicine is the same as Leucogen, which is already authorised in the European Union (EU). The company that makes Leucogen has agreed that its scientific data can be used for Nobivac LeuFel ('informed consent').

How is Nobivac LeuFel used?

Nobivac LeuFel is available as a suspension for injection and can only be obtained with a prescription.

The vaccine is given to cats as an injection under the skin. The initial vaccination course is two injections 3 or 4 weeks apart from 8 weeks of age. In cases where the kitten may have antibodies passed from the mother, a third injection can be given from 15 weeks of age. A booster vaccination of a single injection is necessary one year after the initial vaccination course. Protection starts 3 weeks after the primary course of vaccination and lasts one year. Following the first booster vaccination, protection lasts 3 years.

How does Nobivac LeuFel work?

Nobivac LeuFel is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. Nobivac LeuFel contains small amounts of a protein from the outer layer of the virus called 'envelope p45 protein'. The FeLV protein used in the vaccine is not extracted from viruses but is made in a bacterium using 'recombinant technology'. When a cat is given the vaccine, the cat's immune system recognises the protein as 'foreign' and makes antibodies

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against it. In the future, the immune system will be able to produce antibodies more quickly when it is exposed to FeLV, which will help to protect against the disease caused by the virus.

Nobivac LeuFel also contains aluminium hydroxide gel and extract of *Quillaja saponaria* as adjuvants (ingredients that strengthen the immune response).

What benefits of Nobivac LeuFel have been shown in studies?

In one field study kittens aged 8 to 9 weeks were given an initial vaccination course of Nobivac LeuFel with 2 injections 3 weeks apart and an annual booster injection 1 year later. After the first injection 69% of the kittens had antibodies to FeLV and this increased to 100% after the second injection. Some 64% of cats still had FeLV antibodies before the annual booster, and 100% of cats had FeLV antibodies after the booster.

In a second study, kittens aged 8 to 9 weeks were given an initial vaccination course of a combination vaccine consisting of one dose of Feligen RCP (against feline rhinotracheitis virus, feline calici virus and feline panleucopaenia virus) with one dose of Nobivac LeuFel. After the second injection, 100% of kittens had antibodies to FeLV.

A laboratory study in which cats were exposed to feline leukaemia virus confirmed that following the first annual booster vaccination cats were protected for a three year period against leukaemia.

What are the risks associated with Nobivac LeuFel?

The most common side effects with Nobivac LeuFel (which may affect up to 1 in 10 cats) are a moderate and short-lived local reaction (≤2 cm) after the first injection which resolves without treatment within 3 to 4 weeks, raised body temperature (lasting 1 to 4 days), apathy (listlessness) and digestive disturbances.

Nobivac LeuFel must not be used in pregnant cats.

For the full list of restrictions and all side effects reported with Nobivac LeuFel, see the package leaflet.

What are the precautions for the person who gives the medicine or comes into contact with the animal?

In case of accidental self-injection, medical advice should be sought immediately and the package leaflet or label shown to the doctor.

Why is Nobivac LeuFel authorised in the EU?

The European Medicines Agency decided that Nobivac LeuFel's benefits are greater than its risks and it can be authorised for use in the EU.

Other information about Nobivac LeuFel

Nobivac LeuFel received a marketing authorisation valid throughout the EU for Nobivac LeuFel on 6 November 2017.

This authorisation was based on the authorisation granted to Leucogen in 2009 ('informed consent').

Further information on Nobivac LeuFel can be found on the Agency's website: ema.europa.eu/Find medicine/Veterinary medicines/European public assessment reports.

This overview was last updated in June 2018.