8 September 2017
EMA/CVMP/518494/2017
Committee for Medicinal Products for Veterinary Use

Summary of opinion[1] (initial authorisation)

Nobivac LeuFel

Common name: Feline leukaemia vaccine (inactivated)

On 7 September 2017, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion[2], recommending the granting of a marketing authorisation for the veterinary medicinal product Nobivac LeuFel, suspension for injection, intended for active immunisation of cats from eight weeks of age against feline leukaemia for the prevention of persistent viraemia and clinical signs of the related disease. The applicant for this veterinary medicinal product is Virbac.

Nobivac LeuFel is an inactivated viral vaccine for cats against feline leukaemia (ATCvet code QI06AA01). It contains the purified recombinant p45 FeLV-envelope antigen that was derived from the gp70 surface glycoprotein of the FeLV subgroup A and is expressed in *Escherichia coli* as active substance.

The benefits of Nobivac LeuFel are the active immunisation of cats from eight weeks of age against feline leukaemia for the prevention of persistent viraemia and clinical signs of the related disease. The onset of immunity of the vaccine is 3 weeks after the primary vaccination and the duration of immunity is one year after the primary vaccination. The most common side effects are moderate and transient local swelling, an oedema or a nodule (<2 cm) after the first injection. These local reactions resolve spontaneously within 3 to 4 weeks at the most. After the second injection, and subsequent administrations, this reaction is markedly reduced. In rare cases, pain at palpation, sneezing or conjunctivitis may be noted that resolves without any treatment. Transient common signs following vaccination may also be observed, such as hyperthermia (lasting 1 to 4 days), apathy, digestive disturbances. In very rare cases, anaphylactic reactions have been reported.

Detailed conditions for the use of this product will be described in the summary of product characteristics (SPC) which will be published in the European public assessment report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CVMP, on the basis of quality, safety and efficacy data submitted, considers that there is a

[1] Summaries of opinion are published without prejudice to the Commission Decision, which will normally be issued 67 days from adoption of the opinion.
[2] Applicants may appeal any CVMP opinion, provided they notify the European Medicines Agency in writing of their intention to appeal within 15 days of receipt of the opinion.

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favourable benefit-risk balance for Nobivac LeuFel and therefore recommends the granting of the marketing authorisation.