

22 June 2018
EMA/113131/2018
Committee for Medicinal Products for Veterinary Use

Summary of opinion¹ (post-authorisation)

LEUCOGEN

feline leukaemia vaccine (inactivated)

On 21 June 2018, the Committee for Medicinal Products for Veterinary Use (CVMP) adopted a positive opinion², recommending the granting of a variation to the terms of the marketing authorisation for the veterinary medicinal products LEUCOGEN, LEUCOFELIGEN FeLV/RCP and Nobivac LeuFel. The marketing authorisation holder for these veterinary medicinal products is Virbac S.A.

The change is a modification of the duration of immunity of the feline leukaemia component in all the three products.

The applicant has also taken the opportunity to align the product information for the three products with the latest QRD template version 8.1.

Detailed conditions for the use of these products are described in their updated summary of product characteristics (SPC), for which an updated version reflecting the changes will be published in the revised European public assessment report (EPAR) and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.

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.



¹ Summaries of opinion are published without prejudice to the Commission Decision.