13 May 2022
EMA/CVMP/250532/2022
Committee for Veterinary Medicinal Products

Summary of opinion[1] (post-authorisation)

Suprelorin

International non-proprietary name (INN): deslorelin acetate

On 12 May 2022, the Committee for Veterinary Medicinal Products (CVMP) adopted a positive opinion[2], recommending the granting of a group of variations to the terms of the marketing authorisation for the veterinary medicinal product Suprelorin. The marketing authorisation holder for this veterinary medicinal product is Virbac S.A.

The affected presentation of Suprelorin (4,7 mg implant) is currently authorised for male dogs. The variation is to add a new therapeutic indication in female dogs: for the induction of temporary infertility and to delay the first oestrus and heat signs, and to prevent pregnancy at a young age in intact and healthy sexually immature female dogs; and to add a non-food producing target species for the induction of temporary infertility and suppression of urine odour and of sexual behaviours such as libido, vocalisation, urine marking, and aggressiveness in intact male cats from 3 months of age.

Detailed conditions for the use of this product are described in the 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.

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